SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

NYRSTAR LEACH PRODUCT

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	:	NYRSTAR LEACH PRODUCT
Synonyms	:	leach residues, zinc ore, lead-contg.; NLP (Nyrstar Leach Product), BLP (Balen Leach Product), ALP (Auby Leach Product), BuLP (Budel Leach Product)
Registration number REACH	:	01-2119474886-19-0001 (Nyrstar Belgium NV/SA) 01-2119474886-19-0010 (Nyrstar Budel BV) 01-2119474886-19-0005 (Nyrstar France SAS)
Product type REACH	:	On-site isolated intermediate
	:	Transported isolated intermediate
CAS number	:	91053-49-5
EC number	:	293-314-4

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

1.2.1 Relevant identified uses

The substance is defined as intermediate under Regulation (EC) No 1907/2006, not fulfilling the definition of strictly controlled conditions for which consequently an Article 10 registration is required

IU1: production of the intermediate - During the hydrometallurgical production of zinc and/or zinc-compounds, leach residue and/or gascleaning residues concentrate the Pb- and/or other compounds from the feed. This material is extracted and isolated for further processing.

IU2: Handling and storage of the intermediate: Handling and temporary storage in bulk take place after production and before further processing of the intermediate

IU3: use of the intermediate - The material is unloaded, blended with other, primary and/or secondary materials, and loaded in smelting furnaces (ISA, Blast, convertor, ...) or similar, or in hydrometallurgical steps for further processing and extraction of non-ferrous metals (Pb, Ag, ...) and/or their compounds.

For more detailed information regarding the Identified Uses and the associated Exposure Scenarios: see attached annex

1.2.2 Uses advised against

No uses advised against known

1.3. Details of the supplier of the safety data sheet

Supplier of the safety data sheet

Nyrstar Belgium N.V. on behalf of Nyrstar Sales & Marketing A.G.
Zinkstraat 1
B-2490 Balen
☎ +32 14 44 95 00
🖷 +32 14 81 05 31
infoSDS@nyrstar.com

Nyrstar Budel B.V. on behalf of Nyrstar Sales & Marketing A.G.
Hoofdstraat 1
6024 AA Budel-Dorplein
☎ +32 14 44 96 80
🖷 +32 14 44 95 52
infoSDS@nyrstar.com

Nyrstar France S.A.S. on behalf of Nyrstar Sales & Marketing A.G.
Rue Jean Jacques Rousseau
F-59950 Auby
☎ +32 14 44 96 80
🖷 +33 3 27 88 39 48
infoSDS@nyrstar.com

Manufacturer of the product

Nyrstar Sales & Marketing SA
1 Rue de Jargonnant
CH-1207 Geneva
infoSDS@nyrstar.com

1.4. Emergency telephone number

24h/24h (Telephone advice: English, French, German, Dutch) :

+32 14 58 45 45 (BIG)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

Class	Category	Hazard statements
Carc.	category 1A	H350i: May cause cancer by inhalation.
Muta.	category 1B	H340: May cause genetic defects.
Repr.	category 1A	H360FD: May damage fertility. May damage the unborn child.
Acute Tox.	category 4	H332: Harmful if inhaled.
Acute Tox.	category 4	H302: Harmful if swallowed.
STOT RE	category 2	H373: May cause damage to organs (blood system, central nervous system, lungs, kidneys) through prolonged or repeated exposure.
Eye Dam.	category 1	H318: Causes serious eye damage.
Aquatic Acute	category 1	H400: Very toxic to aquatic life.
Aquatic Chronic	category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2. Label elements

Signal word Danger

H-statements

H350i	May cause cancer by inhalation.
H340	May cause genetic defects.
H360FD	May damage fertility. May damage the unborn child.
H302 + H332	Harmful if swallowed or if inhaled.
H373	May cause damage to organs (blood system, central nervous system, lungs, kidneys) through prolonged or repeated exposure.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.

P-statements

P280	Wear protective gloves, protective clothing and eye protection/face protection.
P260	Do not breathe dust.
P270	Do not eat, drink or smoke when using this product.
P304 + P340	IF INHALED: Remove person to fresh air and keep 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.
P330	Rinse mouth.
P310	Immediately call a POISON CENTER/doctor.

Supplemental information

Restricted to professional users.

2.3. Other hazards

No other hazards known

SECTION 3: Composition/information on ingredients

3.1. Substances

Name REACH Registration No	CAS No EC No	Conc. (C)	Classification according to CLP	Note	Remark
lead(II)sulphate	7446-14-2 231-198-9	C<35%	Repr. 1A; H360Df Acute Tox. 4; H332 Acute Tox. 4; H302 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	(1)(2)(9)(8)(10)	Constituent
diiron zinc tetraoxide	12063-19-3 235-052-5	C<35%			Constituent
calcium sulfate	7778-18-9 231-900-3	C<25%		(2)	Constituent
zinc sulphate (anhydrous)	7733-02-0 231-793-3	C<10%	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	(1)(9)	Constituent
silica, precipitated	112926-00-8	C<25%		(2)	Constituent
barium sulfate	7727-43-7 231-784-4	C<3%		(2)	Constituent

copper sulphate	7758-98-7 231-847-6	C<1%	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Irrit. 2; H315 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	(1)(2)	Constituent
cadmium sulphate	10124-36-4 233-331-6	C<1%	Carc. 1B; H350 Muta. 1B; H340 Repr. 1B; H360FD Acute Tox. 2; H330 Acute Tox. 3; H301 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	(1)(2)(4)(8)(9)(10)	Constituent
manganese sulphate	7785-87-7 232-089-9	C<1%	STOT RE 2; H373 Aquatic Chronic 2; H411	(1)(2)	Constituent
iron arsenate	10102-49-5 233-274-7	C<2.1%	Carc. 1A; H350 Acute Tox. 3; H331 Acute Tox. 3; H301 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	(1)(2)(10)	Constituent
zinc sulphide	1314-98-3 215-251-3	C<4%			Constituent
sulfur	7704-34-9 231-722-6	C<3%	Skin Irrit. 2; H315	(1)	Constituent
magnesium sulphate	7487-88-9 231-298-2	C<1%			Constituent
aluminium oxide	1344-28-1 215-691-6	C<1%		(2)	Constituent
iron sulphide	1317-37-9 215-268-6	C<1%		(2)	Constituent
tin oxide	1332-29-2 215-569-2	C<1%		(2)	Constituent
Iron hydroxide	11113-66-9 234-345-0	C<1%			Constituent
calcium dihydroxide	1305-62-0 215-137-3	C<6%	Eye Dam. 1; H318 Skin Irrit. 2; H315 STOT SE 3; H335	(1)(2)	Constituent

(1) For H-statements in full: see heading 16
(2) Substance with a Community workplace exposure limit
(4) Enumerated in candidate list of substances of very high concern (SVHC) for authorisation (Article 59 of Regulation (EC) No. 1907/2006)
(8) Specific concentration limits, see heading 16
(9) M-factor, see heading 16
(10) Subject to restrictions of Annex XVII of Regulation (EC) No. 1907/2006

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

General:
Check the vital functions. Unconscious: maintain adequate airway and respiration. Respiratory arrest: artificial respiration or oxygen. Cardiac arrest: perform resuscitation. Victim conscious with laboured breathing: half-seated. Victim in shock: on his back with legs slightly raised. Vomiting: prevent asphyxia/aspiration pneumonia. Prevent cooling by covering the victim (no warming up). Keep watching the victim. Give psychological aid. Keep the victim calm, avoid physical strain. Depending on the victim's condition: doctor/hospital.

After inhalation:
Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

After skin contact:
Rinse with water. Do not apply (chemical) neutralizing agents without medical advice. Take victim to a doctor if irritation persists.

After eye contact:
Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply (chemical) neutralizing agents without medical advice. Take victim to an ophthalmologist.

After ingestion:
Rinse mouth with water. Do not apply (chemical) neutralizing agents without medical advice. Consult a doctor/medical service if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

4.2.1 Acute symptoms
After inhalation:

AFTER INHALATION OF FUME: FOLLOWING SYMPTOMS MAY APPEAR LATER: Metal fume fever. Feeling of weakness. Body temperature rise. Headache. Nausea. Vomiting. Metal taste. Muscular pain. Rapid respiration. Respiratory difficulties. Possible oedema of the upper respiratory tract. Risk of lung oedema. Respiratory collapse.

After skin contact:
No effects known.

After eye contact:
Corrosion of the eye tissue. Inflammation/damage of the eye tissue.

After ingestion:
AFTER INGESTION OF HIGH QUANTITIES: Metal taste. Dry/sore throat. Nausea. Vomiting. Abdominal pain. Feeling of weakness. Headache.

4.2.2 Delayed symptoms
No effects known.

4.3. Indication of any immediate medical attention and special treatment needed
If applicable and available it will be listed below.

SECTION 5: Firefighting measures

5.1. Extinguishing media
5.1.1 Suitable extinguishing media:
Adapt extinguishing media to the environment for surrounding fires.

5.1.2 Unsuitable extinguishing media:
Not applicable.

5.2. Special hazards arising from the substance or mixture
On heating (>1000°C): release of toxic and corrosive gases/vapours (lead oxides, sulphur oxides, zinc oxides).

5.3. Advice for firefighters
5.3.1 Instructions:
Dilute toxic gases with water spray. Take account of toxic/corrosive precipitation water. Take account of toxic fire-fighting water. Use water moderately and if possible collect or contain it.

5.3.2 Special protective equipment for fire-fighters:
Gloves (EN 374). Safety glasses (EN 166). Protective clothing (EN 14605 or EN 13034). Dust cloud production: self-contained breathing apparatus (EN 136 + EN 137). Heat/fire exposure: self-contained breathing apparatus (EN 136 + EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Prevent dust cloud formation. No naked flames.

6.1.1 Protective equipment for non-emergency personnel
See heading 8.2

6.1.2 Protective equipment for emergency responders
Gloves (EN 374). Safety glasses (EN 166). Protective clothing (EN 14605 or EN 13034). Dust cloud production: self-contained breathing apparatus (EN 136 + EN 137).

Suitable protective clothing
See heading 8.2

6.2. Environmental precautions
Contain released product, pump into suitable containers. Plug the leak, cut off the supply. Dam up the solid spill. Knock down/dilute dust cloud with water spray. Prevent soil and water pollution. Prevent spreading in sewers.

6.3. Methods and material for containment and cleaning up
Prevent dust cloud formation. Scoop solid spill into closing containers. Carefully collect the spill/leftovers. Clean contaminated surfaces with an excess of water. Take collected spill to manufacturer/competent authority. Wash clothing and equipment after handling.

6.4. Reference to other sections
See heading 13.

SECTION 7: Handling and storage
The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

7.1. Precautions for safe handling
Avoid raising dust. Keep away from naked flames/heat. Observe very strict hygiene - avoid contact. Remove contaminated clothing immediately. Do not discharge the waste into the drain. Avoid dehydratation. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities
7.2.1 Safe storage requirements:
Storage temperature: -15 °C - 35 °C. Meet the legal requirements.

7.2.2 Keep away from:
Heat sources.

7.2.3 Suitable packaging material:
No data available

7.2.4 Non suitable packaging material:

No data available

7.3. Specific end use(s)

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure

a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

EU

Arsenic acid and its salts, as well as inorganic arsenic compounds	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	0.01 mg/m³ (12)
Cadmium and its inorganic compounds	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	0.001 mg/m³ (10)
Calcium dihydroxide	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	1 mg/m³ (2)
	Short time value (Indicative occupational exposure limit value)	4 mg/m³ (2)
Inorganic lead and its compounds	Time-weighted average exposure limit 8 h (Binding occupational exposure limit value)	0.15 mg/m³
Manganese and inorganic manganese compounds (as manganese)	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	0.05 mg/m³ (2)
	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	0.2 mg/m³ (1)
Tin (inorganic compounds as Sn)	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	2 mg/m³

(12): Inhalable fraction. For the copper smelting sector, the limit value shall apply from 11 July 2023
(10): Inhalable fraction. Limit value 0,004 mg/m3 until 11 July 2027. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine.
(2): Respirable fraction
(1): Inhalable fraction

Belgium

Aluminium (métal et composés insolubles, fraction alvéolaire)	Time-weighted average exposure limit 8 h	1 mg/m³
Arsenic et ses composés inorganiques (en As)	Time-weighted average exposure limit 8 h	0.01 mg/m³
Baryum (sulfate de)	Time-weighted average exposure limit 8 h	5 mg/m³
Cadmium et ses composés (particules alvéolaires) (en Cd)	Time-weighted average exposure limit 8 h	0.002 mg/m³
Cadmium et ses composés (particules inhalables) (en Cd)	Time-weighted average exposure limit 8 h	0.01 mg/m³
Calcium (dihydroxyde de) (fraction alvéolaire)	Time-weighted average exposure limit 8 h	1 mg/m³
	Short time value	4 mg/m³
Calcium (sulfate de) (anhydrate, hemihydrate, dihydrate, gypse)	Time-weighted average exposure limit 8 h	10 mg/m³
Cuivre (fumées) (en Cu)	Time-weighted average exposure limit 8 h	0.2 mg/m³
Cuivre (poussières et brouillards de) (en Cu)	Time-weighted average exposure limit 8 h	1 mg/m³
Etain (oxyde et composés inorganiques de; sauf SnH4, en Sn)	Time-weighted average exposure limit 8 h	2 mg/m³
Manganèse et ses composés (en Mn)	Time-weighted average exposure limit 8 h	0.2 mg/m³
Plomb inorg. (poussières et fumées) (en Pb)	Time-weighted average exposure limit 8 h	0.15 mg/m³
Silices amorphes : précipités (gel de silice)	Time-weighted average exposure limit 8 h	10 mg/m³

The Netherlands

Cadmium en anorganische cadmiumverbindingen (als Cd)	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	0.004 mg/m³
Calcium-dihydroxide	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	1 mg/m³
	Short time value (Public occupational exposure limit value)	4 mg/m³
In water onoplosbare zouten van arseenzuur (als As)	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	0.0028 mg/m³
Koper en anorganische koperverbindingen (inhaleerbaar)	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	0.1 mg/m³
Lood en anorganische loodverbindingen	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	0.15 mg/m³
Mangaan en anorganische mangaan-verbindingen (als mangaan)	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	0.05 mg/m³
	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	0.2 mg/m³
Tin (anorganische verbindingen als Sn)	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	2 mg/m³

France

Aluminium (trioxyde de di-)	Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative)	10 mg/m³
Cadmium et ses composés inorganiques (fraction inhalable ou alvéolaire)	Time-weighted average exposure limit 8 h (VRI: Valeur réglementaire indicative)	0.004 mg/m³
Calcium (hydroxyde de) fraction alvéolaire	Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative)	1 mg/m³
	Short time value	4 mg/m³
Calcium (sulfate de)	Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative)	10 mg/m³
Manganèse et ses composés fraction alvéolaire exprimé en manganèse	Time-weighted average exposure limit 8 h (VRI: Valeur réglementaire indicative)	0.05 mg/m³
Manganèse et ses composés fraction inhalable exprimé en manganèse	Time-weighted average exposure limit 8 h (VRI: Valeur réglementaire indicative)	0.20 mg/m³
Plomb métallique et composés, en Pb	Time-weighted average exposure limit 8 h (VRC: Valeur réglementaire contraignante)	0.1 mg/m³

Germany

Blei und anorganischen Bleiverbindungen	Time-weighted average exposure limit 8 h (TRGS 505)	0.1 mg/m³
Calciumdihydroxid	Time-weighted average exposure limit 8 h (TRGS 900)	1 mg/m³
Calciumsulfat	Time-weighted average exposure limit 8 h (TRGS 900)	6 mg/m³
Kieselsäuren, amorphe	Time-weighted average exposure limit 8 h (TRGS 900)	4 mg/m³
Mangan und seine anorganischen Verbindungen	Time-weighted average exposure limit 8 h (TRGS 900)	0.02 mg/m³
	Time-weighted average exposure limit 8 h (TRGS 900)	0.2 mg/m³
Zinn(IV)-Verbindungen, anorganische	Time-weighted average exposure limit 8 h (TRGS 900)	2 mg/m³

UK

Aluminium oxides inhalable dust	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	10 mg/m³
Aluminium oxides respirable dust	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	4 mg/m³
Arsenic and compounds except arsine (as As)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	0.1 mg/m³
Barium sulphate inhalable dust	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	10 mg/m³
Barium sulphate respirable dust	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	4 mg/m³
Cadmium compounds except cadmium oxide fume, cadmium sulphide and cadmium sulphide pigments (as Cd)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	0.025 mg/m³
Calcium hydroxide (Respirable fraction)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	1 mg/m³
	Short time value (Workplace exposure limit (EH40/2005))	4 mg/m³
Calcium hydroxide	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	5 mg/m³
Copper and compounds: dusts and mists (as Cu)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	1 mg/m³
	Short time value (Workplace exposure limit (EH40/2005))	2 mg/m³
Iron salts (as Fe)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	1 mg/m³
	Short time value (Workplace exposure limit (EH40/2005))	2 mg/m³
Lead other than lead alkyls	Time-weighted average exposure limit 8 h (Occupational exposure limit (Control of lead at work))	0.15 mg/m³
Manganese and its inorganic compounds (as Mn) (Inhalable fraction)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	0.2 mg/m³
Manganese and its inorganic compounds (as Mn) (Respirable fraction)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	0.05 mg/m³
Silica, amorphous inhalable dust	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	6 mg/m³
Silica, amorphous respirable dust	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	2.4 mg/m³
Tin compounds, inorganic, except SnH4 (as Sn)	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	2 mg/m³
	Short time value (Workplace exposure limit (EH40/2005))	4 mg/m³

USA (TLV-ACGIH)

Aluminium metal and insoluble compounds	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	1 mg/m³ (R)
Arsenic and inorganic compounds, as As	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	0.01 mg/m³
Barium sulfate	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	5 mg/m³ (I,E)
Cadmium and compounds, as Cd	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	0.002 mg/m³ (R)
	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	0.01 mg/m³
Calcium hydroxide	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	5 mg/m³
Calcium sulfate	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	10 mg/m³ (I)

Lead and inorganic compounds, as Pb	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	0.05 mg/m³
Manganese, elemental and inorganic compounds, as Mn	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	0.1 mg/m³ (I)
Tin and inorganic compounds, excluding Tin hydride and Indium tin oxide, as Sn	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	2 mg/m³ (I)

(R): Respirable fraction
I,E: Inhalable fraction. The value is for particulate matter containing no asbestos and < 1% crystalline silica
(I): Inhalable fraction

b) National biological limit values

If limit values are applicable and available these will be listed below.

Belgium

Plomb et ses composés ioniques (Lood)	sang	70 µg/100ml	

USA (BEI-ACGIH)

Cadmium and inorganic compounds (cadmium)	Blood: not critical	5 µg/L	Background
Cadmium and inorganic compounds (cadmium)	urine: not critical	5 µg/g creatine	Background
Lead and inorganic compounds (Lead)	Blood: not critical	200 µg/L	Women of child bearing potential, whose blood Pb exceeds 10 µg/dl, are at risk of delivering a child with a blood Pb over the current Centers for Disease Control guideline of 10 µg/dl. If the blood Pb of such children remains elevated, they may be at increased risk of cognitive deficits. The blood Pb of these children should be closely monitored and appropriate steps should be taken to minimize the child's exposure to environmental lead.

c) Nationale Akzeptanz- und Toleranzkonzentrationen

Germany

Arsenverbindungen, als Carc. 1A, Carc. 1B eingestuft	Akzeptanzkonzentration (TRGS 910)	0.83 µg/m³
	Toleranzkonzentration (TRGS 910)	8.3 µg/m³ (E) (ÜF: 8)
Cadmium und CdVerbindungen, als Carc.1A, Carc.1B eingestuft	Akzeptanzkonzentration (TRGS 910)	0.16 µg/m³
	Toleranzkonzentration (TRGS 910)	1 µg/m³ (E) (ÜF: 8)

E: Einatembare Fraktion
ÜF: Überschreitungsfaktor

8.1.2 Sampling methods

Product name	Test	Number
Aluminum & Compounds (as Al)	NIOSH	7013
Aluminum Oxide	OSHA	ID 109SG
Arsenic & Compounds (as As)	NIOSH	7900
Cadmium & Cpds (as Cd)	NIOSH	7048
Calciumdihydroxide	NIOSH	7020
Copper Dust and fume	NIOSH	7029
Dialuminiumtrioxide	NIOSH	7013
gel (silica, amorphous)	NIOSH	7501
Iron	OSHA	ID 121
Lead	OSHA	ID 121
Lead	OSHA	ID 125G
Manganese	OSHA	ID 121
Manganese	OSHA	ID 125G
Silica, Amorphous (Respirable)	NIOSH	7501
Sulfites, & Sulfates	NIOSH	6004
Zinc & Cpds (as Zn)	NIOSH	7030

8.1.3 Applicable limit values when using the substance or mixture as intended

If limit values are applicable and available these will be listed below.

8.1.4 Threshold values

DNEL/DMEL - Workers

calcium sulfate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	21.17 mg/m³	
	Acute systemic effects inhalation	5082 mg/m³	

zinc sulphate (anhydrous)

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	1 mg/m³	
	Long-term systemic effects dermal	8.3 mg/kg bw/day	

barium sulfate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	10 mg/m³	
DNEL/DMEL	Long-term local effects inhalation	10 mg/m³	

copper sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	1 mg/m³	
	Long-term local effects inhalation	1 mg/m³	
	Long-term systemic effects dermal	137 mg/kg bw/day	

cadmium sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term local effects inhalation	4 µg/m³	

manganese sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	0.2 mg/m³	
	Long-term systemic effects dermal	0.004 mg/kg bw/day	

zinc sulphide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	5 mg/m³	
	Long-term systemic effects dermal	83 mg/kg bw/day	

magnesium sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	37.6 mg/m³	
	Long-term systemic effects dermal	21.3 mg/kg bw/day	

aluminium oxide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	3 mg/m³	
	Long-term local effects inhalation	3 mg/m³	
	Long-term systemic effects dermal	0.84 mg/kg bw/day	

iron sulphide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	8.82 mg/m³	
	Long-term systemic effects dermal	2.5 mg/kg bw/day	

tin oxide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	2 mg/m³	
	Acute systemic effects inhalation	2 mg/m³	
	Long-term systemic effects dermal	5.7 mg/kg bw/day	
	Acute systemic effects dermal	5.7 mg/kg bw/day	

calcium dihydroxide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term local effects inhalation	1 mg/m³	
	Acute local effects inhalation	4 mg/m³	

DNEL/DMEL - General population

calcium sulfate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	5.29 mg/m³	
	Acute systemic effects inhalation	3811 mg/m³	
	Long-term systemic effects oral	1.52 mg/kg bw/day	
	Acute systemic effects oral	11.4 mg/kg bw/day	

zinc sulphate (anhydrous)

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	1.25 mg/m³	
	Long-term systemic effects dermal	8.3 mg/kg bw/day	
	Long-term systemic effects oral	0.83 mg/kg bw/day	

barium sulfate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	10 mg/m³	
	Long-term systemic effects oral	13000 mg/kg bw/day	

copper sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects oral	0.041 mg/kg bw/day	
	Acute systemic effects oral	0.082 mg/kg bw/day	

cadmium sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects oral	1 µg/kg bw/day	

manganese sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	0.043 mg/m³	
	Long-term systemic effects dermal	0.002 mg/kg bw/day	

zinc sulphide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	2.5 mg/m³	
	Long-term systemic effects dermal	83 mg/kg bw/day	
	Long-term systemic effects oral	0.83 mg/kg bw/day	

magnesium sulphate

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	11.1 mg/m³	
	Long-term systemic effects dermal	12.8 mg/kg bw/day	
	Long-term systemic effects oral	12.8 mg/kg bw/day	

aluminium oxide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	0.75 mg/m³	
	Long-term local effects inhalation	0.75 mg/m³	
	Long-term systemic effects dermal	0.3 mg/kg bw/day	
	Long-term systemic effects oral	1.32 mg/kg bw/day	

iron sulphide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	2.17 mg/m³	
	Long-term systemic effects dermal	1.25 mg/kg bw/day	
	Long-term systemic effects oral	1.25 mg/kg bw/day	

tin oxide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	6 mg/m³	
	Acute systemic effects inhalation	6 mg/m³	
	Long-term systemic effects dermal	2 mg/kg bw/day	
	Acute systemic effects dermal	2 mg/kg bw/day	
	Long-term systemic effects oral	2 mg/kg bw/day	
	Acute systemic effects oral	2 mg/kg bw/day	

calcium dihydroxide

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term local effects inhalation	1 mg/m³	
	Acute local effects inhalation	4 mg/m³	

PNEC

calcium sulfate

Compartments	Value	Remark
STP	100 mg/l	

zinc sulphate (anhydrous)

Compartments	Value	Remark
Fresh water	20.6 µg/l	
Marine water	6.1 µg/l	
STP	100 µg/l	
Fresh water sediment	117.8 mg/kg sediment dw	
Marine water sediment	56.5 mg/kg sediment dw	
Soil	35.6 mg/kg soil dw	

barium sulfate

Compartments	Value	Remark
Fresh water	115 µg/l	
STP	62.2 mg/l	
Fresh water sediment	600.4 mg/kg sediment dw	
Soil	207.7 mg/kg soil dw	

copper sulphate

Compartments	Value	Remark
Fresh water	7.8 µg/l	
Marine water	5.2 µg/l	
STP	230 µg/l	
Fresh water sediment	87 mg/kg sediment dw	
Marine water sediment	676 mg/kg sediment dw	
Soil	65 mg/kg soil dw	

cadmium sulphate

Compartments	Value	Remark
Fresh water	0.19 µg/l	
Marine water	1.14 µg/l	
STP	20 µg/l	
Fresh water sediment	1.8 mg/kg sediment dw	
Marine water sediment	0.64 mg/kg sediment dw	
Soil	0.9 mg/kg soil dw	
Oral	0.16 mg/kg food	

manganese sulphate

Compartments	Value	Remark
Fresh water	0.013 mg/l	
Marine water	0 mg/l	
Aqua (intermittent releases)	0.03 mg/l	
STP	56 mg/l	
Fresh water sediment	0.011 mg/kg sediment dw	
Marine water sediment	0.001 mg/kg sediment dw	
Soil	25.1 mg/kg soil dw	

zinc sulphide

Compartments	Value	Remark
Fresh water	20.6 µg/l	
Marine water	6.1 µg/l	
STP	100 µg/l	
Fresh water sediment	117.8 mg/kg sediment dw	
Marine water sediment	56.5 mg/kg sediment dw	
Soil	35.6 mg/kg soil dw	

magnesium sulphate

Compartments	Value	Remark
Fresh water	0.68 mg/l	
Marine water	0.068 mg/l	
Fresh water (intermittent releases)	6.8 mg/l	
STP	10 mg/l	

tin oxide

Compartments	Value	Remark
Fresh water	0.1 mg/l	
Marine water	0.01 mg/l	
Aqua (intermittent releases)	1 mg/l	
STP	100 mg/l	

calcium dihydroxide

Compartments	Value	Remark
Fresh water	0.49 mg/l	
Fresh water (intermittent releases)	0.49 mg/l	
Marine water	0.32 mg/l	
STP	3 mg/l	
Soil	1080 mg/kg soil dw	

8.1.5 Control banding

If applicable and available it will be listed below.

8.2. Exposure controls

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

8.2.1 Appropriate engineering controls

Avoid raising dust. Keep away from naked flames/heat. Measure the concentration in the air regularly. Carry operations in the open/under local exhaust/ventilation or with respiratory protection.

8.2.2 Individual protection measures, such as personal protective equipment

Observe very strict hygiene - avoid contact. Do not eat, drink or smoke during work.

a) Respiratory protection:

Dust production: dust mask with filter type P3. High dust production: self-contained breathing apparatus (EN 136 + EN 137).

b) Hand protection:

Protective gloves against chemicals (EN 374), Gloves always need to be selected in consultation with the supplier after analysing the specific operating conditions. The glove thickness and breakthrough time can vary per manufacturer, type and model of glove. The technical information of the glove manufacturer always needs to be consulted to ensure the most suitable glove is chosen for each task. The table below serves as an indication and is in compliance with norm EN-420 and EN-374 and other norms, that can be concluded from the risk analysis of the specific operation conditions.

Materials	Measured breakthrough time	Thickness	Protection index	Remark
PVC	> 30 minutes	1.5 mm	Class 2	
butyl rubber	> 120 minutes	0.5 mm	Class 4	
viton	> 480 minutes	0.4 mm	Class 6	

c) Eye protection:

Safety glasses (EN 166). In case of dust production: protective goggles (EN 166).

d) Skin protection:

Dustproof clothing (EN 13982).

8.2.3 Environmental exposure controls:

See headings 6.2, 6.3 and 13

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical form	Solid
Odour	Mild odour
Odour threshold	Not applicable
Colour	Grey-brown
Particle size	No data available (test not performed)
Explosion limits	No data available (test not performed)
Flammability	Not classified as flammable
Log Kow	Not applicable
Dynamic viscosity	Not applicable (solid)
Kinematic viscosity	Not applicable (solid)
Melting point	No data available (test not performed)
Boiling point	No data available (test not performed)
Evaporation rate	Not applicable (solid)
Relative vapour density	Not applicable (solid)
Vapour pressure	Not applicable (solid)
Solubility	No data available (test not performed)
Relative density	1.8 ; ALP
	1.8 ; BLP
	0.8 - 1.2 ; BuLP
Decomposition temperature	No data available (test not performed)
Auto-ignition temperature	No data available (test not performed)
Flash point	Not applicable (solid)
Explosive properties	No chemical group associated with explosive properties
Oxidising properties	No chemical group associated with oxidising properties
pH	< 2 ; ALP
	< 2 ; BLP
	5 ; BuLP

9.2. Other information

Absolute density	1800 kg/m³ ; ALP
	1800 kg/m³ ; BLP
	800 kg/m³ - 1200 kg/m³ ; BuLP

SECTION 10: Stability and reactivity

10.1. Reactivity

Acid reaction. Not corrosive to metals.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Precautionary measures

Avoid raising dust. Keep away from naked flames/heat.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

On heating (>1000°C): release of toxic and corrosive gases/vapours (lead oxides, sulphur oxides, zinc oxides).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Test results

Acute toxicity

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

lead(II)sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral			category 4			Annex VI	
Inhalation			category 4			Annex VI	

calcium sulfate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	OECD 420	> 1584 mg/kg bw		Rat (female)	Experimental value	
Inhalation (dust)	LC50	OECD 403	> 2.61 mg/l air	4 h	Rat (male / female)	Experimental value	

zinc sulphate (anhydrous)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	OECD 401	1710 mg/kg bw		Rat (male)	Experimental value	
Dermal	LD50	OECD 402	> 2000 mg/kg bw	24 h	Rat (male / female)	Experimental value	

silica, precipitated

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50		> 5000 mg/kg		Rat		

barium sulfate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	Equivalent to OECD 401	> 5000 mg/kg		Rat (male)	Experimental value	
Dermal	LD50	OECD 402	> 2000 mg/kg bw		Rat	Read-across	
Inhalation						Data waiving	

copper sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	OECD 401	481 mg/kg		Rat (male / female)	Experimental value	
Dermal	LD50	OECD 402	> 2000 mg/kg	24 h	Rat (male / female)	Experimental value	
Inhalation						Data waiving	

cadmium sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50		225 mg/kg bw(Cd 2+)		Rat (male)	Read-across	
Dermal						Data waiving	
Inhalation (aerosol)	LC50		0.056 mg/l(Cd 2+)	4 h	Rat (male / female)	Read-across	

manganese sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50		2150 mg/kg		Rat (male / female)	Experimental value	
Dermal						Data waiving	
Inhalation (dust)	LC50	OECD 403	> 4.45 mg/l air	4 h	Rat (male / female)	Experimental value	

iron arsenate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	Equivalent to OECD 401	150 mg/kg bw		Mouse (male / female)	Read-across	
Inhalation (aerosol)	LC50	Equivalent to OECD 403	1.04 mg/l	4 h	Mouse (male / female)	Read-across	
Inhalation			category 3			Annex VI	

zinc sulphide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	Equivalent to OECD 401	> 5000 mg/kg		Rat (male / female)	Read-across	
Dermal						Data waiving	
Inhalation (dust)	LC50	OECD 403	> 5.41 mg/l	4 h	Rat (male / female)	Read-across	

sulfur

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	EPA OPP 81-1	> 2000 mg/kg		Rat (male / female)	Experimental value	
Dermal	LD50	EPA OPP 81-2	> 2000 mg/kg	24 h	Rat (male / female)	Experimental value	
Inhalation (dust)	LC50	EPA OPP 81-3	> 5.43 mg/l	4 h	Rat (male / female)	Experimental value	

magnesium sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	OECD 425	> 2000 mg/kg bw		Rat (male / female)	Experimental value	
Dermal	LD50	OECD 402	> 2000 mg/kg	24 h	Rat (male / female)	Experimental value	
Inhalation						Data waiving	

aluminium oxide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	Equivalent to OECD 401	> 15900 mg/kg bw		Rat (male / female)	Experimental value	
Dermal						Data waiving	
Inhalation (aerosol)	LC50	Equivalent to OECD 403	> 2.3 mg/l air	4 h	Rat (male / female)	Experimental value	

iron sulphide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	OECD 425	> 2000 mg/kg bw		Rat (female)	Experimental value	
Dermal	LD50	OECD 402	> 2000 mg/kg bw	24 h	Rat (male / female)	Experimental value	
Inhalation						Data waiving	

calcium dihydroxide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	OECD 425	> 2000 mg/kg bw		Rat (female)	Experimental value	
Dermal	LD50	OECD 402	> 2500 mg/kg bw	24 h	Rabbit (male / female)	Experimental value	
Inhalation (dust)	LC50	OECD 436	> 6.04 mg/l	4 h	Rat (male / female)	Experimental value	

Conclusion

Harmful if swallowed.

Harmful if inhaled.

Not classified as acute toxic in contact with skin

Corrosion/irritation

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

calcium sulfate

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	OECD 405		72 hours	Rabbit	Experimental value	
Skin	Not irritating	OECD 404	4 h	72 hours	Rabbit	Experimental value	

zinc sulphate (anhydrous)

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Highly irritating	OECD 405		1; 24; 48; 72 hrs; 7; 14; 21 days	Rabbit	Experimental value of similar product	Single treatment without rinsing
Eye	Serious eye damage; category 1					Annex VI	
Skin	Not irritating	OECD 404	4 h	1; 24; 48; 72 hours	Rabbit	Experimental value	

barium sulfate

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	OECD 405	1 h	24; 48; 72 hours	Rabbit	Experimental value	
Not applicable (in vitro test)	Not irritating	RHE-model test	15 minutes	15 minutes	Reconstructed human epidermis	Experimental value	

copper sulphate

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Highly irritating	OECD 405	21 day(s)	24; 48; 72 hours	Rabbit	Experimental value	
Skin	Not irritating	OECD 404	4 h		Rabbit	Read-across	Hydrate form
Skin	category 2					Annex VI	

Classification and labelling do not correspond to those of Annex VI

cadmium sulphate

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Not applicable (in vitro test)	Not irritating	OECD 437			Bovine eye (in vitro)	Experimental value	
Not applicable (in vitro test)	Not irritating	OECD 439	15 minutes		Reconstructed human epidermis	Experimental value	

manganese sulphate

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Serious eye damage	OECD 405		24; 48 hours	Rabbit	Experimental value	Single treatment
Skin	Not irritating	OECD 404	4 h	24; 72 hours	Rabbit	Experimental value	

Classification of this substance according to Annex VI is debatable as it does not correspond to the conclusion from the test

zinc sulphide

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Slightly irritating	EU Method B.5	24 h	1; 24; 48; 72 hours	Rabbit	Read-across	Single treatment with rinsing
Skin	Not irritating	Patch test	5 day(s)		Rabbit	Read-across	

sulfur

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	OECD 405		24; 48; 72 hours	Rabbit	Experimental value	
Skin	Irritating	EPA OPP 81-5	4 h	1; 24; 48; 72; 168 hours	Rabbit	Experimental value	

magnesium sulphate

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	OECD 405		24; 48; 72 hours	Rabbit	Read-across	
Not applicable (in vitro test)	Not irritating	EU Method B.46	5 minutes	15 minutes	Reconstructed human epidermis	Read-across	

aluminium oxide

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	Equivalent to OECD 405		24; 48; 72 hrs; 4; 7 days	Rabbit	Experimental value	
Skin	Not irritating	Equivalent to OECD 404	24 h	24; 48; 72 hours	Rabbit	Experimental value	

iron sulphide

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	OECD 405		24; 48; 72 hours	Rabbit	Experimental value	
Skin	Not irritating	OECD 404	4 h	24; 48; 72 hours	Rabbit	Experimental value	

calcium dihydroxide

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Serious eye damage	OECD 405	4 h	1; 24; 48; 72 hours	Rabbit	Experimental value	
	category 2						
Skin	Not irritating	OECD 404	4 h	24; 48; 72 hours	Rabbit	Experimental value	
Inhalation	Irritating; STOT SE cat.3					Literature study	

Conclusion

Causes serious eye damage.
Not classified as irritating to the skin
Not classified as irritating to the respiratory system

Respiratory or skin sensitisation

NYRSTAR LEACH PRODUCT

No (test)data available

Judgement is based on the relevant ingredients

calcium sulfate

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 406	6 h	24; 48 hours	Guinea pig (male)	Experimental value	

zinc sulphate (anhydrous)

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	Equivalent to OECD 429			Mouse (female)	Experimental value	

barium sulfate

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 429			Mouse (female)	Experimental value	

copper sulphate

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 406		24; 48 hours	Guinea pig (male / female)	Experimental value	

cadmium sulphate

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Not applicable (in vitro test)	Limited positive test result	OECD 442D				Experimental value	
Inhalation						Data waiving	

manganese sulphate

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	Equivalent to OECD 429			Mouse (female)	Read-across	

zinc sulphide

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Dermal	Not sensitizing	OECD 406			Guinea pig (female)	Read-across	

sulfur

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 406		24; 48 hours	Guinea pig (male / female)	Experimental value	

magnesium sulphate

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 429			Mouse (female)	Experimental value	

aluminium oxide

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Dermal	Not sensitizing				Guinea pig (male)	Experimental value	
Intratracheal instillation	Not sensitizing				Mouse (male)	Experimental value	

iron sulphide

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 429			Mouse (female)	Experimental value	

calcium dihydroxide

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 429			Mouse (female)	Experimental value	

Conclusion

Not classified as sensitizing for skin

Not classified as sensitizing for inhalation

Specific target organ toxicity

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

lead(II)sulphate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Unknown			STOT RE cat.2					Annex VI
Oral (diet)	Dose level		500 ppm	Blood	Change in the haemogramme/blood composition	7 weeks (daily)	Bovine (male)	Experimental value

calcium sulfate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral	NOAEL	OECD 422	79 mg/kg bw/day	Blood	No effect	35 day(s)	Rat (male)	Experimental value
Oral	LOAEL	OECD 422	237 mg/kg bw/day	Blood	Change in the haemogramme/blood composition	35 day(s)	Rat (male)	Experimental value

zinc sulphate (anhydrous)

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (diet)	NOEL	OECD 408	234 mg/kg bw/day - 243 mg/kg bw/day		No effect	13 weeks (daily)	Rat (male / female)	Experimental value
Dermal								Data waiving
Inhalation (aerosol)	NOAEL	Subchronic toxicity test			No effect	16 weeks (6h / day, 3 days / week)	Rat (male)	Experimental value

barium sulfate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (drinking water)	NOAEL	Subchronic toxicity test	≥ 104 mg/kg bw/day		No effect	92 day(s)	Rat (male / female)	Experimental value
Dermal								Data waiving
Inhalation (dust)	Dose level		40 mg/m³ air		No effect	2 month(s)	Rat	Experimental value

copper sulphate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (diet)	NOAEL	Equivalent to EU Method B.26	1000 ppm		No effect	13 weeks (7 days / week)	Mouse (male / female)	Experimental value
Dermal								Data waiving
Inhalation (aerosol)	NOAEL	OECD 412	≥ 2 mg/m³ air	Lungs	No effect	4 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value

cadmium sulphate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Unknown			STOT RE cat.1					Annex VI
Dermal								Data waiving

manganese sulphate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (diet)	NOAEL	Other	1700 mg/kg bw/day		No effect	13 weeks (daily)	Rat (male)	Read-across
Oral (diet)	NOAEL	Other	2000 mg/kg bw/day		No effect	13 weeks (daily)	Rat (female)	Read-across
Dermal								Data waiving
Inhalation (aerosol)		Subchronic toxicity test		Brain	Haematological changes		Monkey (male)	Experimental value

zinc sulphide

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (diet)	NOAEL	OECD 408	13.26 mg/kg bw/day		No effect	13 week(s)	Rat (male / female)	Read-across

sulfur

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (stomach tube)	NOAEL	OECD 408	1000 mg/kg bw/day		No effect	90 day(s)	Rat (male / female)	Experimental value
Dermal	NOAEL local effects	OECD 410	400 mg/kg bw/day	Skin	No effect	4 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value
Dermal	NOAEL systemic effects	OECD 410	1000 mg/kg bw/day		No adverse systemic effects	4 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value
Inhalation								Data waiving

magnesium sulphate

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (diet)	NOAEL	Equivalent to OECD 453	256 mg/kg bw/day - 284 mg/kg bw/day		No effect	52 week(s)	Rat (male / female)	Read-across
Dermal								Data waiving
Inhalation								Data waiving

aluminium oxide

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (drinking water)	NOAEL	Equivalent to OECD 452	322.5 mg/kg bw/day		No effect	51 week(s)	Rat (male / female)	Read-across
Oral (drinking water)	LOAEL	Equivalent to OECD 452	1075 mg/kg bw/day		neurotoxic effects	51 week(s)	Rat (male / female)	Read-across
Inhalation (dust)	NOAEC	Equivalent to OECD 413	70 mg/m³ air		No effect	26 weeks (6h / day, 5 days / week) - 52 weeks (6h / day, 5 days / week)	Rat	Experimental value

iron sulphide

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (stomach tube)	NOAEL	OECD 422	125 mg/kg bw/day		No effect	42 day(s)	Rat (male)	Experimental value
Oral (stomach tube)	NOAEL	OECD 422	250 mg/kg bw/day		No effect	54 day(s)	Rat (female)	Experimental value
Dermal								Data waiving
Inhalation								Data waiving

calcium dihydroxide

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (stomach tube)	NOAEL	OECD 422	1000 mg/kg bw/day		No effect		Rat (male / female)	Experimental value
Dermal								Data waiving
Inhalation (dust)	NOAEC	OECD 412	0.107 mg/l		No effect	2 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value

Conclusion

May cause damage to organs (blood system, central nervous system, lungs, kidneys) through prolonged or repeated exposure.

Mutagenicity (in vitro)

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

lead(II)sulphate

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	Ames test	Bacteria (S.typhimurium)		Experimental value	

calcium sulfate

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)	No effect	Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 471	Escherichia coli	No effect	Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 476	Mouse (lymphoma L5178Y cells)	No effect	Experimental value	

zinc sulphate (anhydrous)

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 471	Bacteria (S.typhimurium)		Experimental value	

barium sulfate

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 471	Bacteria (S.typhimurium)		Read-across	
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 473	Chinese hamster ovary (CHO)	No effect	Read-across	

copper sulphate

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)		Experimental value	

cadmium sulphate

Result	Method	Test substrate	Effect	Value determination	Remark
Positive		Human lung fibroblasts		Experimental value	
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 471	Bacteria (S.typhimurium)		Read-across	

manganese sulphate

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 473	Human lymphocytes	No effect	Read-across	
Negative	OECD 471	Bacteria (S.typhimurium)	No effect	Read-across	
Negative with metabolic activation, negative without metabolic activation	OECD 476	Mouse (lymphoma L5178Y cells)	No effect	Read-across	

zinc sulphide

Result	Method	Test substrate	Effect	Value determination	Remark
Negative	Equivalent to OECD 471	Bacteria (S.typhimurium)		Read-across	
Negative	OECD 481	Yeast (S. cerevisiae)		Read-across	

sulfur

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 473	Chinese hamster ovary (CHO)		Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)		Experimental value	

magnesium sulphate

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 476	Mouse (lymphoma L5178Y cells)		Experimental value	

aluminium oxide

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 476	Mouse (lymphoma L5178Y cells)		Read-across	
Positive without metabolic activation	Micronucleus test	Human lymphocytes		Read-across	
Positive without metabolic activation	Equivalent to OECD 473	Human lymphocytes		Read-across	

iron sulphide

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)		Experimental value	

calcium dihydroxide

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)		Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 473	Human lymphocytes		Experimental value	

Mutagenicity (in vivo)

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

calcium sulfate

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative	OECD 474		Mouse (male)	Blood	Experimental value

zinc sulphate (anhydrous)

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Intraperitoneal)	Micronucleus test	2 dose(s)/24-hour interval	Mouse (male / female)		Experimental value

copper sulphate

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative	EU Method B.12		Mouse (male / female)		Experimental value

cadmium sulphate

Result	Method	Exposure time	Test substrate	Organ	Value determination
Positive					Annex VI

manganese sulphate

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Oral (stomach tube))	OECD 474		Mouse (female)		Read-across

sulfur

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Oral (stomach tube))	OECD 474	2 dose(s)/24-hour interval	Mouse (male / female)	Bone marrow	Experimental value

aluminium oxide

Result	Method	Exposure time	Test substrate	Organ	Value determination
Ambiguous (Oral (stomach tube))	OECD 474		Rat (female)		Read-across

iron sulphide

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Intraperitoneal)	OECD 474	2 dose(s)/24-hour interval	Mouse (male)	Bone marrow	Read-across

Conclusion

May cause genetic defects.

Carcinogenicity

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

calcium sulfate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral	NOAEL	Other	256 mg/kg bw/day	104 weeks (daily)	Rat (male)	No effect		Experimental value
Oral	NOAEL	Other	284 mg/kg bw/day	104 weeks (daily)	Rat (female)	No effect		Experimental value

zinc sulphate (anhydrous)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (drinking water)	NOAEL	Carcinogenic toxicity study	> 22000 mg/l	52 weeks (daily)	Mouse (male / female)	No carcinogenic effect		Experimental value

barium sulfate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (drinking water)	NOAEL	Carcinogenic toxicity study	≥ 102 mg/kg	105 week(s)	Rat (male / female)	No carcinogenic effect		Read-across

cadmium sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Inhalation (aerosol)	LOAEL	Carcinogenic toxicity study	0.09 mg/m³ air	18 months (daily, 22h / day)	Rat (male / female)	Tumor formation	Lungs	Experimental value

manganese sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (diet)	NOAEL	Carcinogenic toxicity study	615 mg/kg bw	103 weeks (daily)	Rat (male)	No carcinogenic effect		Experimental value
Oral (diet)	NOAEL	Carcinogenic toxicity study	715 mg/kg bw	103 weeks (daily)	Rat (female)	No carcinogenic effect		Experimental value

iron arsenate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (drinking water)	Dose level	Carcinogenic toxicity study	42.5 ppm - 85 ppm	8 days (gestation, daily) - 18 days (gestation, daily)	Mouse (male / female)	Tumor formation	Various organs	Read-across

sulfur

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Unknown								Data waiving

magnesium sulphate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Unknown								Data waiving

aluminium oxide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Inhalation (dust)	NOAEC	Equivalent to OECD 413	50 mg/m³ air	26 weeks (6h / day, 5 days / week)	Rat	No carcinogenic effect		Experimental value

iron sulphide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (drinking water)	NOAEL	OECD 451	320 mg/kg bw/day - 336 mg/kg bw/day	104 week(s)	Rat (male / female)	No carcinogenic effect		Experimental value

calcium dihydroxide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (drinking water)	NOAEL	Carcinogenic toxicity study	2150 mg/kg bw/day - 2280 mg/kg bw/day	104 week(s)	Rat (male / female)	No carcinogenic effect		Read-across

Conclusion

May cause cancer by inhalation.

Reproductive toxicity

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

lead(II)sulphate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity			category 1A					Annex VI
Effects on fertility			category 2					Annex VI

calcium sulfate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity	NOAEL	Equivalent to OECD 414	1600 mg/kg bw/day	10 day(s)	Mouse	No effect	General	Experimental value
	NOAEL	Equivalent to OECD 414	1600 mg/kg bw/day	10 day(s)	Rat	No effect	General	Experimental value
	NOAEL	Equivalent to OECD 414	1600 mg/kg bw/day	13 day(s)	Rabbit	No effect	General	Experimental value
Effects on fertility	NOAEL	OECD 422	790 mg/kg bw/day	2 week(s)	Rat (male / female)	No effect		Experimental value

zinc sulphate (anhydrous)

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	Developmental toxicity study	42.5 mg/kg bw/day	10 day(s)	Rat	No effect		Experimental value
Maternal toxicity (Oral (stomach tube))	NOAEL	Other	42.5 mg/kg bw/day	10 day(s)	Rat	No effect		Experimental value
Effects on fertility (Oral (diet))	Dose level		4000 ppm		Rat (male)	Adverse effect on sperm	Reproductive organs	Experimental value

barium sulfate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	OECD 414	≥ 85.3 mg/kg bw/day	21 days (gestation, daily)	Rat	No effect		Experimental value
Maternal toxicity (Oral (stomach tube))	NOAEL	OECD 414	25.6 mg/kg bw/day	21 days (gestation, daily)	Rat	No effect		Experimental value
Effects on fertility (Oral (drinking water))	NOAEL		4000 ppm		Rat (male / female)	No effect		Experimental value

copper sulphate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity	NOAEL	OECD 414	6 mg/kg bw/day	21 days (gestation, daily)	Rabbit	No effect		Experimental value
Maternal toxicity	NOAEL	OECD 414	6 mg/kg bw/day	21 days (gestation, daily)	Rat	No effect		Experimental value
Effects on fertility	NOAEL	EPA OPPTS 870.3800	1000 ppm - 15000 ppm		Rat (male / female)	No effect		Experimental value

cadmium sulphate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (drinking water))	NOAEL	Developmental toxicity study	5 ppm	14 days (gestation, daily)	Rat	No effect		Read-across
	LOAEL	Developmental toxicity study	50 ppm	14 days (gestation, daily)	Rat	Fetotoxicity	Foetus	Read-across
Maternal toxicity (Oral (drinking water))	NOAEL	Developmental toxicity study	5 ppm	14 days (gestation, daily)	Rat	No effect		Read-across
	LOAEL	Developmental toxicity study	50 ppm	14 days (gestation, daily)	Rat	Maternal toxicity		Read-across
Effects on fertility (Oral (stomach tube))	NOAEL		1 mg/kg bw/day	9 weeks (daily)	Rat (female)	No effect		Read-across
	LOAEL		10 mg/kg bw/day	9 weeks (daily)	Rat (female)	Reduction in the number of pregnancies		Read-across

manganese sulphate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (diet))	NOAEL	Developmental toxicity study		8 week(s) - 10 week(s)	Rat	No effect		Experimental value
Effects on fertility (Oral (drinking water))				12 week(s)	Rat (male)	No effect	Reproductive organs	Experimental value

zinc sulphide

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	Developmental toxicity study	42.5 mg/kg bw/day	10 days (gestation, daily)	Rat	No effect		Read-across
Maternal toxicity (Oral (stomach tube))	NOAEL	Developmental toxicity study	42.5 mg/kg bw/day	10 days (gestation, daily)	Rat	No effect		Read-across
Effects on fertility (Oral (diet))	Dose level		4000 ppm	30 day(s) - 32 day(s)	Rat (male)	Reduction in sperm motility	Male reproductive organ	Read-across

sulfur

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity								Data waiving
Effects on fertility								Data waiving

magnesium sulphate

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	OECD 422	≥ 1500 mg/kg bw/day	28 day(s) - 53 day(s)	Rat	No effect		Read-across
Maternal toxicity (Oral (stomach tube))	NOAEL	OECD 422	≥ 1500 mg/kg bw/day	28 day(s) - 53 day(s)	Rat	No effect		Read-across
Effects on fertility (Oral (stomach tube))	NOAEL	OECD 422	≥ 1500 mg/kg bw/day	4 week(s)	Rat (male / female)	No effect		Read-across

aluminium oxide

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	Equivalent to OECD 414	266 mg/kg bw/day	10 day(s)	Rat	No effect		Read-across
Maternal toxicity (Oral (stomach tube))	NOAEL	Equivalent to OECD 414	266 mg/kg bw/day	10 day(s)	Rat	No effect		Read-across
Effects on fertility (Oral (drinking water))	NOAEL (P)	Equivalent to OECD 426	3225 mg/kg bw/day	> 52 weeks (daily)	Rat (male / female)	No effect		Read-across
Effects on fertility (Oral (stomach tube))	NOAEL	OECD 422	1000 mg/kg bw	28 day(s) - 53 day(s)	Rat (male / female)	No effect		Read-across

iron sulphide

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	OECD 422	500 mg/kg bw/day	42 day(s) - 54 day(s)	Rat	No effect		Experimental value
Maternal toxicity (Oral (stomach tube))	NOAEL	OECD 422	500 mg/kg bw/day	42 day(s) - 54 day(s)	Rat	No effect		Experimental value
Effects on fertility (Oral (stomach tube))	NOAEL	OECD 422	500	42 day(s) - 54 day(s)	Rat (male / female)	No effect	Reproductive organs	Experimental value

calcium dihydroxide

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	Equivalent to OECD 414	≥ 440 mg/kg bw/day	10 days (gestation, daily)	Mouse	No effect		Read-across
Maternal toxicity (Oral (stomach tube))	NOAEL	Equivalent to OECD 414	≥ 440 mg/kg bw/day	10 days (gestation, daily)	Mouse	No effect		Read-across
Effects on fertility (Oral (stomach tube))	NOEL	OECD 422	1000 mg/kg bw/day		Rat (male / female)	No effect		Experimental value

Conclusion

May damage fertility.
May damage the unborn child.

Toxicity other effects

NYRSTAR LEACH PRODUCT

No (test)data available

Chronic effects from short and long-term exposure

NYRSTAR LEACH PRODUCT

Gastrointestinal complaints. Abdominal pain. Nausea. Loss of appetite. Loss of weight. Feeling of weakness. Paleness. Metal taste. Discolouration of the gums. Affection of the renal tissue. Change in urine output. Change in urine composition. Headache. Dizziness. Impairment of the nervous system. Brain affection. Excited/restless. Behavioural disturbances. Emotional instability. Sleeplessness. Impaired memory. Mental confusion. Delusions. Myasthenia. Coordination disorders. Disturbed motor response. Disturbed tactile sensibility. Tremor. Cramps/uncontrolled muscular contractions. Paralysis. Change in the haemogramme/blood composition. Possible premature birth.

SECTION 12: Ecological information

12.1. Toxicity

NYRSTAR LEACH PRODUCT

No (test)data available

Classification is based on the relevant ingredients

lead(II)sulphate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	TLm		7.48 mg/l	96 h	Pimephales promelas			Literature study; Lead ion
Acute toxicity crustacea	LC50		0.3 mg/l	48 h	Daphnia magna			Literature study; Lead ion
Toxicity algae and other aquatic plants	EC50		0.14 mg/l		Selenastrum capricornutum			Literature study; Lead ion

calcium sulfate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50		2980 mg/l	96 h	Lepomis macrochirus			

zinc sulphate (anhydrous)

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50		330 µg/l - 780 µg/l	95 h	Pimephales promelas	Static system	Fresh water	Experimental value; Lethal
Acute toxicity crustacea	EC50	OECD 202	1.4 mg/l - 2.5 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	IC50	OECD 201	136 µg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; Growth rate
	NOEC	OECD 201	24 µg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish	NOEC	OECD 210	56 µg/l - 61 µg/l	116 day(s)	Salmo trutta	Flow-through system	Fresh water	Experimental value
Long-term toxicity aquatic crustacea	NOEC		31 µg/l - 208 µg/l	50 day(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value; Reproduction
Toxicity aquatic micro-organisms	EC50	Equivalent to OECD 209	5.2 mg/l	3 h	Activated sludge	Static system	Fresh water	Experimental value; Respiration

silica, precipitated

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	EC0	OECD 203	≥ 10000 mg/l	96 h	Brachydanio rerio			Literature
Acute toxicity crustacea	EC0	OECD 202	≥ 1000 mg/l	24 h	Daphnia magna			Literature

barium sulfate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	> 174 mg/l	96 h	Danio rerio	Static system	Fresh water	Experimental value; Lethal
Acute toxicity crustacea	LC50		14500 µg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Lethal
Toxicity algae and other aquatic plants	ErC50	OECD 201	> 100 mg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; Nominal concentration
	NOEC	OECD 201	> 100 mg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish	NOEC	OECD 210	≥ 100 mg/l	33 day(s)	Danio rerio	Semi-static system	Fresh water	Experimental value; Growth
Long-term toxicity aquatic crustacea	NOEC	OECD 211	2900 µg/l	3 week(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value; Reproduction
Toxicity aquatic micro-organisms	EC50	OECD 209	> 1000 mg/l	3 h	Activated sludge	Static system	Fresh water	Experimental value; Respiration

copper sulphate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	EPA method, Equivalent to OECD 203	0.193 mg/l	96 h	Pimephales promelas	Flow-through system	Fresh water	Read-across
	LC50		136.5 µg/l	96 h	Pimephales promelas	Static system	Fresh water	Read-across
Acute toxicity crustacea	EC50	OECD 202	0.117 mg/l	48 h	Daphnia magna	Static system	Fresh water	
	EC50	OECD 202	100 µg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value
Toxicity algae and other aquatic plants	ErC50	OECD 201	0.047 mg/l	96 h	Chlamydomonas eugametos	Flow-through system	Fresh water	Weight of evidence
	EC10	OECD 201	2.9 µg/l	72 h	Phaeodactylum	Static system	Salt water	Experimental value
Long-term toxicity fish	NOEC	OECD 204	33 µg/l	330 day(s)	Pimephales promelas	Flow-through system	Fresh water	Experimental value
Long-term toxicity aquatic crustacea	NOEC	OECD 202	6.3 µg/l	7 day(s)	Ceriodaphnia sp.	Semi-static system	Fresh water	Experimental value

cadmium sulphate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	Other	2.5 mg/l	96 h	Jordanella floridae	Flow-through system	Fresh water	Read-across
	LC50		748 µg/l	4 day(s)	Carassius auratus	Flow-through system	Fresh water	Read-across; Nominal concentration
Acute toxicity crustacea	LC50	EPA 600/4-78-012	38 µg/l	48 h	Daphnia magna	Static system	Fresh water	Read-across; Lethal
Toxicity algae and other aquatic plants	EC50	OECD 201	23 µg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Read-across; Biomass
	NOEC	OECD 201	2.4 µg/l	3 day(s)	Pseudokirchneriella subcapitata	Static system	Fresh water	Read-across; Cell numbers
Long-term toxicity fish	NOEC		1.7 µg/l	36 month(s)	Salvelinus fontinalis	Flow-through system	Fresh water	Read-across; Growth rate
Long-term toxicity aquatic crustacea	NOEC		10 µg/l	7 day(s)	Ceriodaphnia dubia	Static renewal	Fresh water	Read-across; Reproduction
Toxicity aquatic micro-organisms	NOEC	OECD 209	200 µg/l	3 h	Activated sludge	Static system	Fresh water	Experimental value; Respiration

manganese sulphate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50		3.17 mg/l	96 h	Oncorhynchus mykiss	Flow-through system	Fresh water	Weight of evidence; Manganese ion
Acute toxicity crustacea	LC50		9.8 mg/l	48 h	Daphnia magna	Static system	Fresh water	Read-across; Manganese ion
Toxicity algae and other aquatic plants	EC50	OECD 201	61 mg/l	72 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value; Growth rate
	NOEC	OECD 201	1 mg/l	72 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish	NOEC	Equivalent to OECD 210	0.76 mg/l	65 day(s)	Oncorhynchus mykiss	Flow-through system	Fresh water	Experimental value; Manganese ion
Long-term toxicity aquatic crustacea	NOEC		0.02 mg/l	20 day(s)	Crassostrea gigas	Static system	Salt water	Experimental value; Growth
Toxicity aquatic micro-organisms	EC50	OECD 209	> 1000 mg/l	3 h	Activated sludge	Static system	Fresh water	Experimental value; Respiration

iron arsenate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	Equivalent to OECD 203	28 mg/l	96 h	Cyprinodon variegatus	Static system	Salt water	Read-across
Acute toxicity crustacea	LC50	APHA	3.26 mg/l	48 h	Daphnia pulex	Static system	Fresh water	Read-across
Toxicity algae and other aquatic plants	ErC50	Equivalent to OECD 201	0.159 mg/l	96 h	Scenedesmus obliquus	Semi-static system	Fresh water	Read-across

zinc sulphide

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	> 0.25 mg/l	96 h	Danio rerio	Static system	Fresh water	Experimental value; GLP
Acute toxicity crustacea	LC50	OECD 202	> 29 µg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; GLP
Toxicity algae and other aquatic plants	ErC50	OECD 201	> 13 µg/l	72 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value; GLP
	NOEC	OECD 201	≥ 13 µg/l	72 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish								Data waiving
Long-term toxicity aquatic crustacea								Data waiving
Toxicity aquatic micro-organisms								Data waiving

sulfur

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC0	OECD 203	> 5 µg/l	96 h	Oncorhynchus mykiss	Semi-static system	Fresh water	Experimental value; Greater than the water solubility
Acute toxicity crustacea	EC50	OECD 202	> 5 µg/l	48 h	Daphnia magna	Semi-static system	Fresh water	Experimental value; Greater than the water solubility
Toxicity algae and other aquatic plants	NOEC	OECD 201	> 5 µg/l	72 h	Algae	Semi-static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish								Data waiving
Long-term toxicity aquatic crustacea	NOEC	OECD 211	> 2.5 µg/l	21 day(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value; Reproduction
Toxicity aquatic micro-organisms								Data waiving

magnesium sulphate

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	EPA 600/4-90/027	680 mg/l	96 h	Pimephales promelas	Static system	Fresh water	Read-across; Lethal
	LC50		15500 mg/l	96 h	Gambusia affinis	Static system		
Acute toxicity crustacea	LC50	EPA 600/4-90/027	720 mg/l	48 h	Daphnia magna	Static system	Fresh water	Read-across
	EC50		1700 mg/l	24 h	Daphnia magna			
Toxicity algae and other aquatic plants	EC50		2700 mg/l	18 day(s)	Chlorella vulgaris	Static system	Fresh water	Read-across; Cell numbers
Long-term toxicity fish								Data waiving
Long-term toxicity aquatic crustacea								Data waiving
Toxicity aquatic micro-organisms	EC50		84 g/l	30 minutes	Photobacterium phosphoreum			Experimental value

aluminium oxide

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50		> 100 mg/l	96 h	Salmo trutta			Literature study
Acute toxicity crustacea	EC50		> 100 mg/l	48 h	Daphnia magna			Literature study

iron sulphide

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50		> 10000 mg/l	96 h	Gambusia affinis	Static system		Experimental value
Acute toxicity crustacea								Data waiving
Toxicity algae and other aquatic plants								Data waiving
Long-term toxicity fish								Data waiving
Long-term toxicity aquatic crustacea								Data waiving
Toxicity aquatic micro-organisms								Data waiving

	Parameter	Method	Value	Duration	Species	Value determination
Toxicity soil macro-organisms						Data waiving
Toxicity soil micro-organisms						Data waiving
Toxicity terrestrial plants						Data waiving
Toxicity other terrestrial organisms						Data waiving

calcium dihydroxide

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	50.6 mg/l	96 h	Oncorhynchus mykiss	Static system	Fresh water	Experimental value; Lethal
Acute toxicity crustacea	EC50	OECD 202	49.1 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	EC50	OECD 201	184.57 mg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; Growth rate
	NOEC	OECD 201	48 mg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity aquatic crustacea	NOEC		32 mg/l	14 day(s)	Crangon sp.	Semi-static system	Salt water	Experimental value; Growth
Toxicity aquatic micro-organisms	EC50	OECD 209	300.4 mg/l	3 h	Activated sludge	Static system	Fresh water	Experimental value; Respiration

Conclusion

Very toxic to aquatic life.
Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

copper sulphate

Biodegradation water

Method	Value	Duration	Value determination
			Data waiving

manganese sulphate

Biodegradation water

Method	Value	Duration	Value determination
			Data waiving

Biodegradation soil

Method	Value	Duration	Value determination
			Data waiving

zinc sulphide

Biodegradation water

Method	Value	Duration	Value determination
			Data waiving

Half-life water (t1/2 water)

Method	Value	Primary degradation/mineralisation	Value determination
			Data waiving

sulfur

Biodegradation water

Method	Value	Duration	Value determination
			Data waiving

Phototransformation air (DT50 air)

Method	Value	Conc. OH-radicals	Value determination
Other	4.25 h; GLP		Experimental value

Biodegradation soil

Method	Value	Duration	Value determination
			Data waiving

iron sulphide

Biodegradation water

Method	Value	Duration	Value determination
			Data waiving

Half-life water (t1/2 water)

Method	Value	Primary degradation/mineralisation	Value determination
			Data waiving

Conclusion

Water

No test data of component(s) available

12.3. Bioaccumulative potential

NYRSTAR LEACH PRODUCT

Log Kow

Method	Remark	Value	Temperature	Value determination
	Not applicable			

lead(II)sulphate

Log Kow

Method	Remark	Value	Temperature	Value determination
		1.13		Estimated value

diiron zinc tetraoxide

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

calcium sulfate

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

zinc sulphate (anhydrous)

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF		0.4 - 7.51	45 day(s)	Channa punctatus	Experimental value

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

silica, precipitated

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

barium sulfate

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF		1.2 l/kg - 74.4 l/kg		Lepomis macrochirus	Experimental value

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

copper sulphate

Log Kow

Method	Remark	Value	Temperature	Value determination
				Not applicable

cadmium sulphate

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF		1385; Fresh weight	92 day(s)	Salmo salar	Read-across

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

manganese sulphate

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
					Data waiving

BCF other aquatic organisms

Parameter	Method	Value	Duration	Species	Value determination
					Data waiving

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

iron arsenate

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

zinc sulphide

BCF other aquatic organisms

Parameter	Method	Value	Duration	Species	Value determination
BCF		38 - 28960; Fresh weight	28 day(s)	Palaemon elegans	Experimental value

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

sulfur

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
					Data waiving

BCF other aquatic organisms

Parameter	Method	Value	Duration	Species	Value determination
					Data waiving

Log Kow

Method	Remark	Value	Temperature	Value determination
		0.23		Estimated value

magnesium sulphate

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

aluminium oxide

Log Kow

Method	Remark	Value	Temperature	Value determination
	Not applicable (inorganic)			

iron sulphide

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
					Data waiving

BCF other aquatic organisms

Parameter	Method	Value	Duration	Species	Value determination
					Data waiving

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

tin oxide

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

Iron hydroxide

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

calcium dihydroxide

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

Conclusion

Contains bioaccumulative component(s)

12.4. Mobility in soil

cadmium sulphate

(log) Koc

Parameter	Method	Value	Value determination
			Data waiving

zinc sulphide

(log) Koc

Parameter	Method	Value	Value determination
			Data waiving

sulfur

(log) Koc

Parameter	Method	Value	Value determination
			Data waiving

magnesium sulphate

(log) Koc

Parameter	Method	Value	Value determination
			Data waiving

iron sulphide

(log) Koc

Parameter	Method	Value	Value determination
			Data waiving

Conclusion

No (test)data on mobility of the components available

12.5. Results of PBT and vPvB assessment

The criteria of PBT and vPvB as listed in Annex XIII of Regulation (EC) No 1907/2006 do not apply to inorganic substances.

12.6. Other adverse effects

NYRSTAR LEACH PRODUCT

Greenhouse gases

Not included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014)

Ozone-depleting potential (ODP)

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

copper sulphate

Groundwater

Groundwater pollutant

cadmium sulphate

Groundwater

Groundwater pollutant

magnesium sulphate

Groundwater

Groundwater pollutant

calcium dihydroxide

Groundwater

Groundwater pollutant

SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

13.1. Waste treatment methods

13.1.1 Provisions relating to waste

European Union

Hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.
Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).
01 03 07* (wastes from physical and chemical processing of metalliferous minerals: other wastes containing hazardous substances from physical and chemical processing of metalliferous minerals). Depending on branch of industry and production process, also other waste codes may be applicable.

13.1.2 Disposal methods

Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Do not discharge into drains or the environment. Dispose of at authorized waste collection point. Do not discharge into surface water (Directive 2000/60/EC, Council Decision 2455/2001/EC).

13.1.3 Packaging/Container

European Union

Waste material code packaging (Directive 2008/98/EC).
15 01 10* (packaging containing residues of or contaminated by dangerous substances).

SECTION 14: Transport information

Road (ADR)

14.1. UN number

UN number	3077

14.2. UN proper shipping name

Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (lead(II) sulphate; zinc sulphate (anhydrous))

14.3. Transport hazard class(es)

Hazard identification number	90
Class	9
Classification code	M7

14.4. Packing group

Packing group	III
Labels	 9

14.5. Environmental hazards

Environmentally hazardous substance mark	 yes

14.6. Special precautions for user

Special provisions	274
Special provisions	335
Special provisions	375
Special provisions	601
Limited quantities	Combination packagings: not more than 5 kg per inner packaging for solids. A package shall not weigh more than 30 kg. (gross mass)

Rail (RID)

14.1. UN number

UN number	3077

14.2. UN proper shipping name

Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (lead(II) sulphate; zinc sulphate (anhydrous))

14.3. Transport hazard class(es)

Hazard identification number	90
Class	9
Classification code	M7

14.4. Packing group

Packing group	III
Labels	 9

14.5. Environmental hazards

Environmentally hazardous substance mark	 yes

14.6. Special precautions for user

Special provisions	274
Special provisions	335
Special provisions	375
Special provisions	601
Limited quantities	Combination packagings: not more than 5 kg per inner packaging for solids. A package shall not weigh more than 30 kg. (gross mass)

Inland waterways (ADN)

14.1. UN number

UN number	3077

14.2. UN proper shipping name

Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (lead(II) sulphate; zinc sulphate (anhydrous))

14.3. Transport hazard class(es)

Class	9
Classification code	M7

14.4. Packing group

Packing group	III
Labels	 9

14.5. Environmental hazards

Environmentally hazardous substance mark	 yes

14.6. Special precautions for user

Special provisions	274
Special provisions	335
Special provisions	375
Special provisions	601
Limited quantities	Combination packagings: not more than 5 kg per inner packaging for solids. A package shall not weigh more than 30 kg. (gross mass)

Sea (IMDG/IMSBC)

14.1. UN number

UN number	3077

14.2. UN proper shipping name

Proper shipping name	environmentally hazardous substance, solid, n.o.s. (lead(II) sulphate; zinc sulphate (anhydrous))

14.3. Transport hazard class(es)

Class	9

14.4. Packing group

Packing group	III

Labels	 9

14.5. Environmental hazards

Marine pollutant	P
Environmentally hazardous substance mark	 yes

14.6. Special precautions for user

Special provisions	274
Special provisions	335
Special provisions	966
Special provisions	967
Special provisions	969
Limited quantities	Combination packagings: not more than 5 kg per inner packaging for solids. A package shall not weigh more than 30 kg. (gross mass)

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Annex II of MARPOL 73/78	Not applicable

14.8 Specific information

MARPOL Annex V	In accordance with the International Maritime Organization's (IMO) amendments to MARPOL Annex V, with effect from 1 January 2013 onwards, this material is classified as harmful to the marine environment
IMSBC-code	Cargo group A and B – MHB (TX, CR)
Bulk Cargo Shipping Name	LEAD CONCENTRATE, leach product

Air (ICAO-TI/IATA-DGR)

14.1. UN number

UN number	3077

14.2. UN proper shipping name

Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (lead(II) sulphate; zinc sulphate (anhydrous))

14.3. Transport hazard class(es)

Class	9

14.4. Packing group

Packing group	III
Labels	 9

14.5. Environmental hazards

Environmentally hazardous substance mark	 yes

14.6. Special precautions for user

Special provisions	A158
Special provisions	A179
Special provisions	A197
Special provisions	A97

Passenger and cargo transport

Limited quantities: maximum net quantity per packaging	30 kg G

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European legislation:

VOC content Directive 2010/75/EU

VOC content	Remark
	Not applicable (inorganic)

Prior informed consent (PIC) - listed ingredient

Contains component(s) listed in Annex I of Regulation (EU) No 649/2012: Part 1 - List of chemicals subject to export notification procedure

European drinking water standards (Directive 98/83/EC)

lead(II)sulphate

Parameter	Parametric value	Note	Reference
Lead	10 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

calcium sulfate

Parameter	Parametric value	Note	Reference
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

zinc sulphate (anhydrous)

Parameter	Parametric value	Note	Reference
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

copper sulphate

Parameter	Parametric value	Note	Reference
Copper	2 mg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

cadmium sulphate

Parameter	Parametric value	Note	Reference
Cadmium	5 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Pesticides	0.1 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Pesticides — Total	0.5 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

manganese sulphate

Parameter	Parametric value	Note	Reference
Manganese	50 µg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

iron arsenate

Parameter	Parametric value	Note	Reference
Arsenic	10 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Iron	200 µg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

magnesium sulphate

Parameter	Parametric value	Note	Reference
Sulphate	250 mg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

aluminium oxide

Parameter	Parametric value	Note	Reference
Aluminium	200 µg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

iron sulphide

Parameter	Parametric value	Note	Reference
Iron	200 µg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

Iron hydroxide

Parameter	Parametric value	Note	Reference
Iron	200 µg/l		Listed in Annex I, Part C, of Directive 98/83/EC on the quality of water intended for human consumption.

REACH Candidate list

Contains component(s) included in candidate list of substances of very high concern (SVHC) for authorisation (Article 59 of Regulation (EC) No 1907/2006)

REACH Annex XVII - Restriction

Contains component(s) subject to restrictions of Annex XVII of Regulation (EC) No 1907/2006: restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

	Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
· lead(II)sulphate	Lead sulphates; PbSO 4	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
· iron arsenate	Arsenic compounds	1.Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment. 2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use. 3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market. 4. By way of derogation from paragraph 3: a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorised in accordance with Article 5(1) of Directive 98/8/EC. Wood so treated shall not be placed on the market before fixation of the preservative is completed. b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely: — as structural timber in public and agricultural buildings, office buildings, and industrial premises, — in bridges and bridgework, — as constructional timber in freshwater areas and brackish waters, for example jetties and bridges, — as noise barriers, — in avalanche control, — in highway safety fencing and barriers, — as debarked round conifer livestock fence posts, — in earth retaining structures, — as electric power transmission and telecommunications poles, — as underground railway sleepers. c) Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that all treated wood placed on the market is individually labelled “For professional and industrial installation and use only, contains arsenic”. In addition, all wood placed on the market in packs shall also bear a label stating “Wear gloves when handling this wood. Wear a dust mask and eye protection when cutting or otherwise crafting this wood. Waste from this wood shall be treated as hazardous by an authorised undertaking”. d) Treated wood referred to under point a) shall not be used: — in residential or domestic constructions, whatever the purpose, — in any application where there is a risk of repeated skin contact, — in marine waters, — for agricultural purposes other than for livestock fence posts and structural uses in accordance with point (b), — in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption. 5. Wood treated with arsenic compounds that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life. 6. Wood treated with CCA type C that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4: — may be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (d), — may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d). 7. Member States may allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007: — to be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (d), — to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
· cadmium sulphate	Cadmium and its compounds	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (OJ L 256, 7.9.1987, p. 42). 1. Shall not be used in mixtures and articles produced from synthetic organic polymers (hereafter referred to as plastic material) such as:

			— polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] — polyurethane (PUR) [3909 50] — low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] — high-density polyethylene (HDPE) [3901 20] — acrylonitrile butadiene styrene (ABS) [3903 30] — poly(methyl methacrylate) (PMMA) [3906 10]. Mixtures and articles produced from plastic material shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (OJ L 365, 31.12.1994, p. 10) and acts adopted on its basis. By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted. 2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article. 3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons. 4. By way of derogation, paragraph 1, second subparagraph shall not apply to: — mixtures produced from PVC waste, hereinafter referred to as “recovered PVC”, — mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications: (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences, and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: “Contains recovered PVC” or with the following pictogram: Pictogram recovered PVC In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017. 5. For the purpose of this entry, “cadmium plating” means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of:

		— industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89]. 7. However, the restrictions in paragraphs 5 and 6 shall not apply to: — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011
· cadmium sulphate · iron arsenate	Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: “Restricted to professional users”. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists’ paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
· cadmium sulphate	Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively.	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: “Restricted to professional users”. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists’ paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

· lead(II)sulphate · cadmium sulphate	Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: “Restricted to professional users”. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists’ paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
· lead(II)sulphate	Lead and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. (*) OJ L 326, 29.12.1969, p. 36. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly. 7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. 8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/EEC; (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87) unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 °C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight;

		(h) the tips of writing instruments; (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European Parliament and of the Council (*); (iv) Directive 2011/65/EU of the European Parliament and of the Council (**) 9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016. (*) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1). (**) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).
· cadmium sulphate	The substances listed in column 1 of the Table in Appendix 12	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. 4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**). 5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation. 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly. (*) Regulation (EU) 2016/425 of the European Parliament and of the Council of of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51). (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).
· iron arsenate	The substances listed in column 1 of the Table in Appendix 12	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. 4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**). 5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation. 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.

		(*) Regulation (EU) 2016/425 of the European Parliament and of the Council of of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51). (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).
· lead(II)sulphate	The substances listed in column 1 of the Table in Appendix 12	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. 4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**). 5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation. 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly. (*) Regulation (EU) 2016/425 of the European Parliament and of the Council of of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51). (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

National legislation Belgium

NYRSTAR LEACH PRODUCT

No data available

cadmium sulphate

Additional classification	Cadmium et ses composés (particules alvéolaires) (en Cd); C; La mention "C" signifie que l'agent en question relève du champ d'application de l'arrêté royal du 2 décembre 1993 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents cancérigènes et mutagènes et reprotoxiques au travail.
	Cadmium et ses composés (particules inhalables) (en Cd); C; La mention "C" signifie que l'agent en question relève du champ d'application de l'arrêté royal du 2 décembre 1993 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents cancérigènes et mutagènes et reprotoxiques au travail.

iron arsenate

Additional classification	Arsenic et ses composés inorganiques (en As); C; La mention "C" signifie que l'agent en question relève du champ d'application de l'arrêté royal du 2 décembre 1993 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents cancérigènes et mutagènes et reprotoxiques au travail.

tin oxide

Résorption peau	Etain (oxyde et composés inorganiques de; sauf SnH4, en Sn); D; La mention "D" signifie que la résorption de l'agent, via la peau, les muqueuses ou les yeux, constitue une partie importante de l'exposition totale. Cette résorption peut se faire tant par contact direct que par présence de l'agent dans l'air.

National legislation The Netherlands

NYRSTAR LEACH PRODUCT

Waterbezwaarlijkheid	Z (1); Algemene Beoordelingsmethodiek (ABM)

lead(II)sulphate

SZW - Lijst van voor de voortplanting giftige stoffen (ontwikkeling)	loodverbindingen, alle; 1A; May damage the unborn child.
SZW - Lijst van voor de voortplanting giftige stoffen (vruchtbaarheid)	loodverbindingen, alle; 2; Suspected of damaging fertility.

cadmium sulphate

SZW - Lijst van kankerverwekkende stoffen	Cadmiumsulfaat; Listed in SZW-list of carcinogenic substances
SZW - Lijst van mutagene stoffen	Cadmiumsulfaat; Listed in SZW-list of mutagenic substances
SZW - Lijst van voor de voortplanting giftige stoffen (ontwikkeling)	Cadmiumsulfaat; 1B; May damage the unborn child.
SZW - Lijst van voor de voortplanting giftige stoffen (vruchtbaarheid)	Cadmiumsulfaat; 1B; May damage fertility.

manganese sulphate

SZW - Lijst van voor de voortplanting giftige stoffen (ontwikkeling)	Mangaan en -verbindingen; 2; Suspected of damaging the unborn child.
SZW - Lijst van voor de voortplanting giftige stoffen (vruchtbaarheid)	Mangaan en -verbindingen; 2; Suspected of damaging fertility.

iron arsenate

SZW - Lijst van kankerverwekkende stoffen	inorganische arseenverbindingen; Listed in SZW-list of carcinogenic substances
SZW - Lijst van voor de voortplanting giftige stoffen (ontwikkeling)	inorganische arseenverbindingen; 1B; May damage the unborn child.
SZW - Lijst van voor de voortplanting giftige stoffen (vruchtbaarheid)	inorganische arseenverbindingen; 1B; May damage fertility.
SZW - Lijst van voor de voortplanting giftige stoffen (borstvoeding)	inorganische arseenverbindingen; May cause harm to breastfed babies

National legislation France

NYRSTAR LEACH PRODUCT

No data available

lead(II)sulphate

Catégorie cancérogène	Plomb métallique et composés, en Pb; (C1A,C1B,C2)
Catégorie toxique pour la reproduction	Plomb métallique et composés, en Pb; (R1A,R1B,R2)

cadmium sulphate

Catégorie cancérogène	Cadmium et ses composés inorganiques (fraction inhalable ou alvéolaire); (C1A,C1B,C2)
Catégorie mutagène	Cadmium et ses composés inorganiques (fraction inhalable ou alvéolaire); (M1A,M1B,M2)
Catégorie toxique pour la reproduction	Cadmium et ses composés inorganiques (fraction inhalable ou alvéolaire); (R1A,R1B,R2)

National legislation Germany

NYRSTAR LEACH PRODUCT

WGK	3; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017

lead(II)sulphate

TA-Luft	5.2.2/II

diiron zinc tetraoxide

TA-Luft	5.2.1

calcium sulfate

TA-Luft	5.2.1

zinc sulphate (anhydrous)

TA-Luft	5.2.1

silica, precipitated

TA-Luft	5.2.1
TRGS900 - Risiko der Fruchtschädigung	Kieselsäuren, amorphe; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes nicht befürchtet zu werden

barium sulfate

TA-Luft	5.2.1

copper sulphate

TA-Luft	5.2.1

cadmium sulphate

TA-Luft	5.2.7.1.1/I
TRGS905 - Krebserzeugend	Cadmium-Verbindungen (in Form atembarer Stäube/Aerosole), ausgenommen: die nachfolgend genannten sowie, die in Anhang VI Teil 3 der CLP-Verordnung namentlich aufgeführten, soweit sie "geringer eingestuft" sind; 1B

manganese sulphate

TA-Luft	5.2.2/III
TRGS900 - Risiko der Fruchtschädigung	Mangan und seine anorganischen Verbindungen; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes nicht befürchtet zu werden
	Mangan und seine anorganischen Verbindungen; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes nicht befürchtet zu werden

iron arsenate

TA-Luft	5.2.7.1.1/I

zinc sulphide

TA-Luft	5.2.1

sulfur

TA-Luft	5.2.1

magnesium sulphate

TA-Luft	5.2.1

aluminium oxide

TA-Luft	5.2.1

iron sulphide

TA-Luft	5.2.1

calcium dihydroxide

TA-Luft	5.2.1
TRGS900 - Risiko der Fruchtschädigung	Calciumdihydroxid; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes nicht befürchtet zu werden

National legislation United Kingdom

NYRSTAR LEACH PRODUCT

No data available

cadmium sulphate

Carcinogen	Cadmium compounds except cadmium oxide fume, cadmium sulphide and cadmium sulphide pigments (as Cd); Carc

iron arsenate

Carcinogen	Arsenic and compounds except arsine (as As); Carc

Other relevant data

NYRSTAR LEACH PRODUCT

No data available

lead(II)sulphate

TLV - Carcinogen	Lead and inorganic compounds, as Pb; A3

silica, precipitated

IARC - classification	3; Silica

cadmium sulphate

TLV - Carcinogen	Cadmium and compounds, as Cd; A2
	Cadmium and compounds, as Cd; A2

manganese sulphate

TLV - Carcinogen	Manganese, elemental and inorganic compounds, as Mn; A4

iron arsenate

TLV - Carcinogen	Arsenic and inorganic compounds, as As; A1

aluminium oxide

TLV - Carcinogen	Aluminium metal and insoluble compounds; A4

15.2. Chemical safety assessment

A chemical safety assessment has been performed.

SECTION 16: Other information

Full text of any H-statements referred to under heading 3:

H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H331 Toxic if inhaled.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H340 May cause genetic defects.
H350 May cause cancer.
H350i May cause cancer by inhalation.
H360Df May damage the unborn child. Suspected of damaging fertility.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H373 May cause damage to organs (brain) through prolonged or repeated exposure if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.
H373 May cause damage to organs (blood system, central nervous system, lungs, kidneys) through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.

(*)	INTERNAL CLASSIFICATION BY BIG
ADI	Acceptable daily intake
AOEL	Acceptable operator exposure level
CLP (EU-GHS)	Classification, labelling and packaging (Globally Harmonised System in Europe)
DMEL	Derived Minimal Effect Level

DNEL	Derived No Effect Level
EC50	Effect Concentration 50 %
ErC50	EC50 in terms of reduction of growth rate
LC50	Lethal Concentration 50 %
LD50	Lethal Dose 50 %
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative & Toxic
PNEC	Predicted No Effect Concentration
STP	Sludge Treatment Process
vPvB	very Persistent & very Bioaccumulative

M-factor

lead(II)sulphate	1	Acute	BIG
zinc sulphate (anhydrous)	1	Acute	ECHA
zinc sulphate (anhydrous)	1	Chronic	ECHA
cadmium sulphate	10	Acute	ECHA
cadmium sulphate	10	Chronic	ECHA
iron arsenate	1	Acute	BIG

Specific concentration limits CLP

lead(II)sulphate	C ≥ 2,5 %	Repr. 2; H361f	CLP Annex VI (ATP 0)
	C ≥ 0,5 %	STOT RE 2; H373	CLP Annex VI (ATP 0)
cadmium sulphate	C ≥ 0,01 %	Carc. 1B; H350	CLP Annex VI (ATP 0)
	C ≥ 7 %	STOT RE 1; H372	CLP Annex VI (ATP 0)
	0,1 % ≤ C < 7%	STOT RE 2; H373	CLP Annex VI (ATP 0)

1. Exposure scenarios

1.1. Exposure scenario 1: production of the intermediate

Full title: Industrial isolation of the Intermediate Leach.Pb.residue (293-314-4), from Zinc-metallurgical leaching and gascleaning steps, by settling, filtering and other hydrometallurgical processes.

Table 1. Exposure scenario 1 for the intermediate Pb-leach residue.

Exposure Scenario Format (1) addressing uses carried out by workers
Title of exposure scenario Leach.Pb.residue 1: Industrial isolation of the Intermediate Leach.Pb.residue (293-314-4), from Zinc-metallurgical leaching and gascleaning steps, by settling, filtering and other hydrometallurgical processes.
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant; SU: 3, 8, 14 PROC: 2, 3, 8b, 9, 26 PC: 19 AC: not applicable ERC: 1
Further explanations (if needed) During the hydrometallurgical production of zinc and/or zinc-compounds, unleached residue and/or gascleaning residues -'Leach.Pb.residue'-concentrate the Pb-compounds from the feed; they are extracted and isolated for further processing in production units of Lead metal or Lead compounds.
Exposure Scenario
1.1.1 Contributing scenario (1) controlling environmental exposure for the Industrial isolation of the Intermediate Leach.Pb.residue (293-314-4), from Zinc-metallurgical leaching and gas cleaning steps, by settling, filtering and other hydrometallurgical processes.
Further specification: • Solutions from leaching tanks or gas-cleaning washing towers may contain unleached material, steriles and insoluble sulphates, i.e. Lead- and calcium-sulphate. • Separation of those solids occurs in semi-closed settlers and, further if needed, the leachate may be filtered on adapted filters, • Further storage outside, in covered "loges", after press-filtering i.o.t. reduce the moisture to 25-35%. • Occasionally, the filtercake may be treated in a rotary dryer • Transfer of the Pb-rich Intermediate occurs in big-bags or containers or covered bulk load trucks, according to applicable regulation • This Intermediate is typically used in production units of Lead metal or Lead compounds. (EC 231-100-4)

Maintenance activities

Product characteristics

Product related conditions:

The Leach. Pb residue is a wet filtercake with an average Lead-content of 15-70% w/w

Amounts used

Daily and annual amount per site:

maximum 400000 T/y

Frequency and duration of use

Continuous production

Environment factors not influenced by risk management

Flow rate of receiving surface water:

Default is used unless specified otherwise

Other given operational conditions affecting environmental exposure

Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process (via air and waste water); dry or water based processes; conditions related to temperature and pressure; indoor or outdoor use of products; work in confined area or open air;

Typically hydrometallurgical process steps: leaching tanks, settlers, filters

Potential dryers are operated under strong aspiration (negative pressure towards atmospheric pressure)

- Besides the process waters, some non-process waters can be generated containing zinc (e.g. from cleaning)
- All processes are performed in a confined area. All residues containing zinc/Lead are recycled.

Technical conditions and measures at process level (source) to prevent release

Process design aiming to prevent releases and hence exposure to the environment; this includes in particular conditions ensuring rigorous containment; performance of the containment to be specified (e.g. by quantification of a release factor in section 9.x.2 of the CSR);

- Process enclosures and closed circuits where relevant and possible.
- Containment of liquid volumes in sumps to collect/prevent accidental spillage, acid solutions are treated adequately.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; specify effectiveness of measures;
specify the size of industrial sewage treatment plant (m3/d), degradation effectiveness and sludge treatment (if applicable);

- On-site waste water treatment techniques can be applied to prevent releases to water (if applicable) e.g.: chemical precipitation, sedimentation and filtration (efficiency 90-99.98%).
- Containment of liquid volumes in sumps to collect/prevent accidental spillage
- Air emissions are controlled by use of cyclones, baghouse filters, scrubbers,

demisters and/or other air emission abatement devices e.g. filters (up to 99% efficiency), wet scrubbers (50-99% efficiency). This may create a general negative pressure at the system openings (loading, sampling, production exit).

Organizational measures to prevent/limit release from site

Specific organisational measures or measures needed to support the functioning of particular technical measures.

- In general, emissions are controlled and prevented by implementing an integrated management system e.g. ISO 9000, ISO 1400X series, or alike, and, when applicable, by being IPPC-compliant (cf. NFM-BREF).

  Such management system should include general industrial practice like e.g.:
  - The substance/ UVCB is rigorously contained by technical means during the whole lifecycle including manufacture, purification, cleaning/maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
  - Procedural and control technologies shall be used that minimise emission and any resulting exposure
  - Only properly trained and authorised personnel handles the substance
  - For cleaning/maintenance, special procedures such as system purging and washing before opening devices
  - Procedures, control technologies for accidents and waste
  - Substance-handling procedures well documented and strictly supervised
- Treatment and monitoring of releases to outside air, and exhaust gas streams (process & hygiene), according to national regulation.
- SEVESO 2 compliance, if applicable

Conditions and measures related to municipal sewage treatment plant

Size of municipal sewage system/treatment plant (m3/d); specify degradation effectiveness; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable); please note*: the default size of the municipal STP (2000 m_3/d) will be rarely changeable for downstream uses.*

In cases where applicable: default size, unless specified otherwise.

Conditions and measures related to external treatment of waste for disposal

Fraction of used amount transferred to external waste treatment for disposal; type of suitable treatment for waste generated by work-ers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste; specify effectiveness of treatment;

- If any, all hazardous wastes are treated by certified contractors according to EU and

national legislation.

Conditions and measures related to external recovery of waste

Fraction of used amount transferred to external waste treatment for recovery: specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery out-side waste incinerators; specify effectiveness of measure;

- All residues formed during the leaching process and gascleaning system, are recovered and either recycled in the system or handled further according the waste legislation.
- Users of Zn/Pb and Zn/Pb-compounds, have to favour the recycling channels of the end-of-life products
- Users of Zn/Pb and Zn/Pb-compounds have to minimize Zn/Pb-containing waste, promote recycling routes and, for the remaining, dispose the waste streams according the Waste regulation.

1.1.2 Contributing scenario (2) controlling worker exposure for the Industrial isolation of the Intermediate Leach Pb residue (293-314-4), from Zinc-metallurgical leaching and gascleaning steps, by settling, filtering and other hydrometallurgical processes.

Name of contributing scenario 2:

During the hydrometallurgical production of zinc and/or zinc-compounds, unleached residue and/or gascleaning residues -'Leach.Pb.residue'-concentrate the Pb-compounds from the feed; they are extracted and isolated for further processing in production units of Lead metal or Lead compounds.

Further specification

Product characteristic

Product related conditions, e.g. the concentration of the substance in a mixture, the physical state of that mixture (solid, liquid; if solid: level of dustiness), package design affecting exposure)

- The substance/ UVCB is a wet filtercake,
- With occasional (sampling, cleaning, maintenance) and potentially direct exposure for workers
- The average Zinc content lies between 20-55% W/W and Lead content between 20-70% w:w
- Copper compounds (up to 10% w/w Pb) and Cadmium compounds (up to 10% w/w Cd) are possibly present

Amounts used

Amounts used at a workplace (per task or per shift); note: sometimes this information is not needed for assessment of worker's expo-sure

Maximum 1200 T/day, 400T/shift

Frequency and duration of use/exposure

Duration per task/activity (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure

8hrs shift

Human factors not influenced by risk management

Particular conditions of use, e.g. body parts potentially exposed as a result of the nature of the activity

Uncovered body parts: (potentially) face

Other given operational conditions affecting workers exposure

Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process into workers environment; room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature and pressure.

- All processes are carried out in confined areas with a minimum of operators
- The process is managed and controlled from a separate control-room.

Technical conditions and measures at process level (source) to prevent release

Process design aiming to prevent releases and hence exposure of workers; this in particular includes conditions ensuring rigorous containment; performance of containment to be specified (e.g. by quantification of residual losses or exposure)

- Local exhaust ventilation on work areas with potential dust/aerosols generation, dust capturing and removal techniques
- Process enclosures closed circuits or semi-enclosures where appropriate.
- Containment of liquid volumes in sumps to collect/prevent accidental spillage

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

Engineering controls, e.g. exhaust ventilation, general ventilation; specify effectiveness of measure

- Local exhaust ventilation systems (generic LEV(84%)); for dryers, higher efficiencies are required (95-99%)
- Cyclones/baghouse filters/ demisters (for minimizing air emissions) : efficiency: 70-90% (cyclones), 50-80% (dust filters), 85-95% (baghouse filters, scrubbers)
- Process enclosure, especially in potentially dusty units
- Dust control: dust and Zn/Pb in dust/aerosols needs to be measured in the workplace air (static or individual) according to national regulations.
- Special care for the general establishment and maintenance of a clean working environment by e.g.:
    - Cleaning of process equipment and workshop
    - Storage of calcines in dedicated silos

Organisational measures to prevent /limit releases, dispersion and exposure

Specific organisational measures or measures needed to support the functioning of particular technical measures (e.g. training and supervision).

- In general, an integrated management system is implemented on the workplace e.g.

ISO 9000, ISO ICS13100 series, or alike, and, when applicable, by being IPPC-compliant

Such management system should include general industrial practice like e.g.:

- The substance/ UVCB is rigorously contained by technical means during the whole lifecycle including manufacture, purification, cleaning/maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
- Procedural and control technologies shall be used that minimise emission and any resulting exposure
- Only properly trained and authorised personnel handles the substance
- For cleaning/maintenance, special procedures such as system purging and washing before opening devices
- Procedures, control technologies for accidents and waste
- Substance-handling procedures well documented and strictly supervised

- Additionally, in case of need, personal protection measures (see below) are recommended

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

Personal protection, e.g. wearing of gloves, face protection, full body dermal protection, goggles, respirator; specify effectiveness of measure; specify the suitable material for the PPE (where relevant) and advise how long the protective equipment can be used before replacement (if relevant)

Wearing of gloves and protective clothing is compulsory (efficiency >=90%).

With normal handling, no respiratory personal protection (breathing apparatus) is necessary. If risk for exceedance of OEL/DNEL, use e.g.:

-dust filter-half mask P1 (efficiency 75%)

-dust filter-half mask P2 (efficiency 90%)

-dust filter-half mask P3 (efficiency 95%)

-dust filter-full mask P1 (efficiency 75%)

-dust filter-full mask P2 (efficiency 90 %)

-dust filter-full mask P3 (efficiency 97.5%)

Eyes: safety glasses are recommended

Exposure assessment

A. *Workers*

The intermediate “Pb-leach residue”, is produced in the “leaching/purification” section of the zinc production plant. This process step involves essentially wet processes. Recent monitored data have been reported for Zn, Cd, Pb, As, and other metals in workplace air (table below). All data provided in table below are measured for given individual workers at the same workplace area (“leaching/purification”) at different times. For each individual, the specific value of the measurement and the geomean value of the different measurements are reported. For the assessment, the full range of the observed individual geomean values is compared with the DNEL.

Technical specifications of the monitoring:

All measurements were performed by personal sampler (unless indicated otherwise), during the period 2012-2013.

Samples 1-7: (personal)

-sampling device: Gilair 5

-filter type : Millipore 0.8µm cassette type ‘cyclone’, all inhalable fraction

-method of analysis: internal lab, ISO 9901 certified, ICPMS

-error before and after measurement: <5%

Samples 8-9: static sampling

-sampling device: Staplex high volume sampler

-filter type : TFA#41, HVS casette (inhalable fraction)

-method of analysis: internal lab, ISO 9901 certified, ICPMS

-error before and after measurement: <5%

For the human health assessment of the intermediate, the metals contained in table below are considered relevant. See also table 2.

Results are given in table below.

Table 2. Geomean of monitored metal concentrations in workplace air (µg/m3) at the leaching/purification section of the zinc plant. Personal samplers, geomean results given by individual worker. The original data are available from IZA.

Metal in workplace air (µg/m3)	Number of samples (year)	Arsenic	Cadmium	Lead	Nickel	Zinc	Copper
Leaching 1	2		1.3	29.9		36.8	

	(2012)						
2	5 (2013)	0.1	0.1	3.6		17.2	
3	3 (2013)	0.1	0.1	2.1		13.7	
4	3 (2013)	0.1	0.1	1.9		21.5	
5	4 (2013)	0.1	0.05	0.7	0.1	5.9	
6	2 (2013)	0.2	1.5	9.4			
7	3 (2013)						0.7
8	2 (2013)	0.1	0.21	24.1			
9	2 (2013)	0.1	0.8	6.3			
DNEL inhalation local (mg/m3) long term		0.01-0.05 (inhal) OEL	0.004(resp)	0.05-0.15 (inhal) OEL	0.05	5(slightly sol); 1.25 (soluble)	1(inhal)
Risk ratio		0.002-0.02	0.00001-0.15*	0.005-0.6	0.002	0.001-0.03	0.0007

*considering a factor inhalable-respirable of 2.5

Discussion

In this assessment, the focus is put on the possible local inhalatory effects of the metals that are considered most critical in a workplace situation, also in a context of combined exposure. The monitoring data demonstrate that the different metals contained in the intermediate do not result in risk for local inhalatory effects. Risk ratios for local inhalation effect are <<1, due to the risk management measures applied and the wet nature of the processes involved.

So it can be concluded from this quantitative assessment that no inhalation risk is predicted when the risk management measures as indicated in the exposure scenario are applied.

Dermal contact with substances at the workplace is linked to workplace air levels (contact through deposition from air, and contact with contaminated surfaces). Direct contact (through e.g. immersion) is not relevant.

There are no direct data on dermal exposure. For the metals Pb, Cd and As, dermal exposure is integrated in the biomonitoring for these substances that is routinely performed at the plants. More importantly, it is noted that workplace concentrations of As and Cd are very low, as follows from table above. For the metal present in more significant levels, i.e. Pb, it is known that Pb is most easily taken up by inhalation or ingestion, and that dermal uptake is negligible in terms of systemic uptake, as compared to the other routes of exposure. So, according to the qualitative assessment, considering the elements above in combination with the very low exposure levels in the workplace air, no risks are predicted for dermal effects, neither. It is emphasised that workers constantly wear protective clothing, including special gloves.

In addition to the data mentioned in table above, occasional measurements demonstrate that workplace levels of Cr, Cu, Sb, Al and Mn were also very low (at or close to detection level).

B. Environment

The zinc plant has a closed water circuit, with no emissions to the surface waters. So no risk is predicted for the aquatic freshwater surface waters and sediments.

The leaching/purification section of the plant, where the intermediate is formed, involves essentially wet processes. The emissions to air from this section are considered insignificant.

The endpoints STP, and marine waters/sediments are not relevant for the plant of this assessment (no emissions to STP and not located on coastal area, respectively).

1.2 Exposure scenario 2: storage and handling of the intermediate

Full title: Industrial storage and handling in bulk of the Intermediate Leach.residue, zinc ore, Pb containing (293-314-4), from Zinc-metallurgical leaching and gas-cleaning steps.

Table 4. Exposure scenario 2 for the intermediate „leach residue, zinc ore, Pb containing“.

Exposure Scenario Format (1) addressing uses carried out by workers
Title of exposure scenario Leach residue, zinc ore, Pb containing 2: Industrial storage and handling in bulk of the Intermediate “Leach.residue, zinc ore, Pb containing” (293-314-4), from Zinc-metallurgical leaching and gascleaning steps
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant; SU: 9, 14 PROC: 8a, 8b, 9 PC: “Technical function: intermediate (precursor)” AC: not applicable ERC: 6a
Further explanations (if needed) The intermediate “Leach residue, zinc ore, Pb containing” is in most cases transported, handled and stored in bulk volume. This scenario describes the possible exposure and risk management of bulk storage and handling.
Exposure Scenario
1.2.1 Contributing scenario (1) controlling environmental exposure for Industrial storage and handling in bulk of the Intermediate Leach.residue, zinc ore, Pb containing (293-314-4), from Zinc-metallurgical leaching and gascleaning steps
Further specification: • After press-filtering to reduce volume, transfer of the Pb-rich Intermediate occurs in big-bags or containers or covered bulk load trucks, according to applicable regulation • Unloading of trucks/train wagons in the storage area • Further storage inside in covered “loges” (after press-filtering to reduce moisture to 16-40% - Occasionally, the filter cake may be treated in a rotary dryer) • Loading of trucks or train wagons or cargo-ships or transfer in big-bags and containers • Maintenance activities take place
Product characteristics
Product related conditions: The Leach residue, zinc ore, Pb containing is a wet filter cake with an average Lead-content

of 8-70% w/w and a moisture content of 16-27%
Amounts used
Daily and annual amount per site: maximum 400000 T/y
Frequency and duration of use
Continuous production, intermittent storage and handling of large volumes
Environment factors not influenced by risk management
Flow rate of receiving surface water: Default is used unless specified otherwise
Other given operational conditions affecting environmental exposure
Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process (via air and waste water); dry or water based processes; conditions related to temperature and pressure; indoor or outdoor use of products; work in confined area or open air; • All processes are performed in a dedicated area. • Bulk intermediate is unloaded from the truck/ship and stored indoors in large hangars on concrete floor. The bulk material is stored in dedicated warehouse. Each product is stored in a separate pile. If appropriate, water sprinklers may be used for keeping the moisture content at required level, or as an option to minimize dust formation. The stockpile is handled by bulldozer. • The material is reloaded in ship by large crane (volume 4m³). • All waters on the quay are guided to the sewage system by the slightly inclined slope of the quay. The quay is cleaned regularly. • All water residues (from precipitation, cleaning, sprinkling,…) are collected and treated in an on-site water purification system involving flocculation and filtration (and possibly other systems). After treatment, the water is discharged into the local surface water (dock).
Technical conditions and measures at process level (source) to prevent release
Process design aiming to prevent releases and hence exposure to the environment; this includes in particular conditions ensuring rigorous containment; performance of the containment to be specified (e.g. by quantification of a release factor in section 9.x.2 of the CSR); • Ships are docked as close as possible to the dock edge to optimize operations.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and

releases to soil

Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; this includes strictly controlled conditions (procedural and control technology) to minimise emissions; specify effectiveness of measures;
specify the size of industrial sewage treatment plant (m3/d), degradation effectiveness and sludge treatment (if applicable);

- On-site water treatment
- Prevention of leakage of waters into the dock waters by slight inclination of quay surface to collection points
- Indoor areas are ventilated by natural air flow. Outdoor handling of materials may result in local dust formation. Dust deposited in work area is collected by cleaning machines and transported to the cleaning water system.

Organizational measures to prevent/limit release from site

Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions.

- In general, emissions are controlled and prevented by implementing an integrated management system e.g. ISO 9000 or alike, and, when applicable, by being IPPC-compliant (cf. NFM-BREF).

  Such management system, aiming at ensuring controlled conditions, should include general industrial practice like e.g.:
  - The substance/ UVCB is rigorously contained by technical means during the whole lifecycle including manufacture, purification, cleaning/maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
  - Procedural and control technologies shall be used that minimize emission and any resulting exposure
  - Only properly trained and authorized personnel handle the substance
  - For cleaning/maintenance, special procedures such as system purging and washing before opening devices
  - Procedures, control technologies for accidents and waste
  - Substance-handling procedures well documented and strictly supervised
- Treatment and monitoring of releases to outside air, and exhaust gas streams

(process & hygiene) is possible, according to national regulation.

- SEVESO compliance, if applicable

Conditions and measures related to municipal sewage treatment plant
Size of municipal sewage system/treatment plant (m3/d); specify degradation effectiveness; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable); please note: the default size of the municipal STP (2000 m3/d) will be rarely changeable for downstream uses. In cases where applicable: default size, unless specified otherwise.
Conditions and measures related to external treatment of waste for disposal
Fraction of used amount transferred to external waste treatment for disposal; type of suitable treatment for waste generated by work-ers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste; specify effectiveness of treatment; • If any, all hazardous wastes are treated by certified contractors according to EU and national legislation.
Conditions and measures related to external recovery of waste
Fraction of used amount transferred to external waste treatment for recovery: specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery out-side waste incinerators; specify effectiveness of measure; • All captured residues formed during the activities are recovered and either recycled in the system or handled further according the waste legislation. • Users of Zn/Pb and Zn/Pb-compounds, have to favour the recycling channels of the end-of-life products • Users of Zn/Pb and Zn/Pb-compounds have to minimize Zn/Pb-containing waste, promote recycling routes and, for the remaining, dispose the waste streams according the Waste regulation.

1.2.2 Contributing scenario (2) controlling worker exposure for Industrial storage and handling in bulk of the Intermediate Leach.residue, zinc ore, Pb containing (293-314-4), from Zinc-metallurgical leaching and gas cleaning steps
Name of contributing scenario 2:

The intermediate “Leach residue, zinc ore, Pb containing” is in most cases transported, handled and stored in bulk volume. This scenario describes the storage and handling in bulk steps.

Further specification

Worker exposure during handling and storage of this bulk material highly depends on the nature of the work: outdoor or indoor, enclosed (e.g. in a closed cabin with positive air pressure and/or filtering or personal respiratory protection equipment), duration and frequency of the exposure,… etc. In defined exposure situations, personal respiratory protection equipment is used. Given the wide variability of these determining factors, the exposures will be assessed for each function specifically.

Product characteristic

Product related conditions, e.g. the concentration of the substance in a mixture, the physical state of that mixture (solid, liquid; if solid: level of dustiness), package design affecting exposure)

- The substance/ UVCB is a wet filter cake, with moisture content of 16-40 %
- With occasional (handling, sampling, cleaning, maintenance) and potentially direct exposure for workers
- The average Zinc content lies between 20-55% W/W, and Lead content between 8-70% w:w
- Copper compounds (up to 10% w/w Pb) and Cadmium compounds (up to 10% w/w Cd) are possibly present

Amounts used

Amounts used at a workplace (per task or per shift); note: sometimes this information is not needed for assessment of worker’s expo-sure

Maximum 1200 T/day

Frequency and duration of use/exposure

Duration per task/activity (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure

As indicated

Human factors not influenced by risk management

Particular conditions of use, e.g. body parts potentially exposed as a result of the nature of the activity

Uncovered body parts: (potentially) face; when potential exposure to dust, respiratory

protection is applied.

Other given operational conditions affecting workers exposure

Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process into workers environment; room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature and pressure.

- All processes are carried out in dedicated areas with a minimum of operators

Technical conditions and measures at process level (source) to prevent release

Process design aiming to prevent releases and hence exposure of workers; this in particular includes conditions ensuring rigorous containment; performance of containment to be specified (e.g. by quantification of residual losses or exposure)

- Several activities are carried out outdoors.
- Bulk materials are stored indoor in separate open boxes/silos/piles.
- Materials with high dustiness may be humidified by sprinkling
- All waters (cleaning, precipitation) are collected and treated in on site purification system.

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

Engineering controls, e.g. exhaust ventilation, general ventilation; specify effectiveness of measure

- Special care for the general establishment and maintenance of a clean working environment by e.g.:
  - Cleaning of process equipment and workshop
  - Storage of materials in dedicated storage location

Organisational measures to prevent /limit releases, dispersion and exposure

Specific organisational measures or measures needed to support the functioning of particular technical measures (e.g. training and supervision). Those measures need to be reported in particular for demonstrating strictly controlled conditions (to justify exposure based waiving).

- In general, an integrated management system is implemented on the workplace e.g. ISO 9000, ISO ICS13100 series, or alike, and, when applicable, by being IPPC-compliant

  Such management system, aiming at ensuring controlled conditions, should include general industrial practice like e.g.:

- The substance/ UVCB is rigorously contained by technical means during the whole lifecycle including manufacture, purification, cleaning/maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
- Procedural and control technologies shall be used that minimize emission and any resulting exposure
- Only properly trained and authorized personnel handle the substance
- For cleaning/maintenance, special procedures such as system purging and washing before opening devices
- Procedures, control technologies for accidents and waste
- Substance-handling procedures well documented and strictly supervised, e.g.:
  - Workers take into account wind direction when being near material, e.g. sampler will sample at the above-wind side of material.
  - Truck drivers will stay in cabin while loading/unloading, with ventilation turned off

- Additionally, in case of need, personal protection measures are recommended (see below)

Conditions and measures related to personal protection, hygiene and health evaluation
Personal protection, e.g. wearing of gloves, face protection, full body dermal protection, goggles, respirator; specify effectiveness of measure; specify the suitable material for the PPE (where relevant) and advise how long the protective equipment can be used before replacement (if relevant) Wearing of gloves and protective clothing is compulsory (efficiency >=90%). With normal handling, no respiratory personal protection (breathing apparatus) is necessary. If risk for exceedance of OEL/DNEL, use e.g.: -dust filter-half mask P1 (Assigned Protection Factor (APF) 4) -dust filter-half mask P2 (APF 10) -dust filter-half mask P3 (APF 20) -dust filter-full mask P1 (APF 4) -dust filter-full mask P2 (APF 10) -dust filter-full mask P3 (APF 40) Eyes: safety goggles (e.g. EN 166) are recommended

Exposure assessment

1. Environment

The bulk materials are treated in isolated volumes on concrete surface during the whole process of unloading, storage and reloading. Spreading by wind is prevented by storage indoors and possible spraying. Emissions to local water (dock) are prevented by collecting all waters (precipitation, cleaning, ..) in a water treatment system.

Surface waters

The exposure is assessed based on monitored data in the dock (table 5)

Table 5: Monitored metal concentrations (dissolved fraction) and water parameters in the dock at the site. Since long-term effects are considered, mean values are used.

metal	Zn	Pb	Cd
Concentration in dock water (µg/l)	21	1.3	0.15
PNEC bioavailable*	47 (bioavailability 23%)	6.5 (bioavailability calculated with DOC correction only)	0.25 (EQS for high hardness: > 250mg CaCO3)
PEC/PNEC	0.45	0.2	0.6

*Bioavailability parameters: pH 7.0, TOC: 5.4mg/l; hardness “very high” (113°F)

Discussion:

The PEC/PNEC values for surface water of the dock indicate no risks for the main metals involved. In terms of combining the exposures, it is emphasised that the combined effect of these metals is antagonistic and that summation would result in an overestimation of the risk; e.g. it is well documented that presence of zinc protects against the uptake of Cd by organisms. Taking also into account that in these calculations background exposure has been included (background should be subtracted to calculate local added risk), it is concluded that there are no risks predicted for the surface water if the risk management measures as described in the scenario, are applied.

Regarding the combined risk of metals for the aquatic environment, combined toxicity effects are not clear at present , and simple summation of the risk ratios based on measured concentrations is not scientifically justified (see section 10, under “current thinking – environment”) for discussion.

Man via the environment

During unloading and reloading of the materials dust may be formed that may be blown to immediate surroundings of the site. The “Man via environment” scenario analyses the potential exposure of populations living in the surroundings of the site through inhalation of ambient air, dietary consumption of locally grown food, consumption of local groundwater for drinking water. Given the localisation of the site in an exclusively industrial environment, the absence of habitation in the surroundings of the site, the absence of agricultural activity and drinking water abstraction, this scenario is considered not relevant.

The Flemish Environment Agency (VMM) monitors metals in suspended air on a few measuring points in Flanders, e.g. in urban Antwerp, but not in Antwerp harbor. Measurements in „urban“ Antwerp air for e.g. Cd are similar to background“ : <1 ng Cd/m3 (https://www.vmm.be/data/zware-metalen/zware-metalen#section-2).

The endpoints STP, and marine waters/sediments are not relevant for this local scenario (no emissions to STP and not located or emitting on coastal area, respectively).

2. Workers

The intermediate “Pb-leach residue”, is produced in the “leaching/purification” section of the zinc production plant. This process step involves essentially wet processes. After drying, during which the moisture content is brought to 16-40 %, the resulting Pb leach residue is transported and stored as a humid (moist) material.

In the current assessment of occupational exposure of workers involved in the handling of the intermediate during loading/unloading/storage, individual monitoring data are used by preference (table 6). Given the composition of the substance, exposures to zinc, lead and cadmium are considered relevant.

Monitored data on workers

In table 6a, individual monitored exposure data are given for job descriptions at the storage and handling site. Workers are monitored individually by personal samplers. The workplace air is monitored; in case the air levels exceed or are close to the occupational standards, the worker uses personal respiratory protection devices as indicated. This way of working is generally applied in practice.

Table 6a: individual monitoring data* (inhalable fraction, µg/m3) and resulting exposure taking into account personal respiratory protection, of workers handling Pb-leach residue in bulk at handling and storage site of Pb-leach residue.

Job description	Pb workplace air	Cd workplace air	Pb exposure with RPE	Cd exposure with RPE	Sum risk ratios
Foreman	27,5	0,55	NA	NA	0,6

Driver front loader	17,3	<0,24	NA	NA	0,37
Maintenance in station and installations	254	4,12	6,35**	0,10	0,14
Electrician	40,2	0,72	10***	0,18	0,22

*data from May 2016; Apparatus – sampling train containing air sampling pump cf. EN 1076, tubing and a sampler for sampling inhalable dust cf. ISO 7708 (IOM sampler with cassette filled with MCE filter 25 mm 0,8 µm)
**use of full-face mask P3 when possibility for exposure
***use of half-face mask P1 when possibility for exposure

In addition, in table 6b, individual monitored exposure data are given for workers that have job descriptions similar to the exposures the receiving site of storage and handling of the intermediate. Workers are monitored individually by personal samplers.

Table 6b. Individual monitoring data* (inhalable fraction, µg/m3) and resulting exposure of workers handling Pb-leach residue in bulk at the site where the bulk intermediate material after production is and handled and loaded in a way similar to the practice at the site of storage and handling.

Job description	Sampling period	Fraction	Zn	Pb	Cd	Sum risk ratios
Operator Pb leach product*	24-2-2014	Inhalable**	53	6,1	0,43	0,17
	27-2-2014		55	6,3	0,37	0,18
	3-3-2014		173	16,2	1,1	0,38
	6-3-2014		19	2,2	0,14	0,10
	23-11-2015		56	6,5	0,51	0,19
	24-11-2015		92	10,2	1,04	0,33
geomean			61	6,7	0,5	0,20
Payloader Pb leach		respirable	Zn	Pb	Cd	

product***						
	4-3-2014		31	3,7	0,29	*5
	5-3-2014		33	2,6	0,14	
	7-3-2014		14	1,4	0,12	
	10-3-2014		36	4,1	0,27	
	30-11-2015		23	1,9	0,12	
	4-12-2015		17	1,5	0,12	
geomean			24	2,3	0,2	

*this job description is similar to the sampling job at the storage/handling site.

**apparatus: gilair plus; filter: MCE 25 mm 0,8µm; sampler: IOM inhalable sampler ;

***job description similar to handling material at storage/handling site

****apparatus: gilair plus; filter: Millipore MCE 25 mm 0,8µm; Sampler: type cassella SIMPEDS HD plastic cyclone.

In the handling and storage, a specific task can be performed which is related to the filling of (usually big) bags. In this specific activity, which is performed in bagging campaigns at an irregular frequency, exposure can be higher due to formation of local dust in the direct surroundings of the workers. The exposure situation under such conditions was specifically monitored and the data are presented in table 6c.

While at the level of the respirable fraction, the concentrations are below the DNELs (e.g. Cd), a number of DNELs expressed as inhalable fraction are exceeded for a number of metals (As, Cu, Pb). These figures reflect general workplace conditions; it is thus in the first place necessary to apply additional risk management measures at the general workplace level. As a main measure, it is proposed to apply local exhaust ventilation at the operation. This is expected to already improve the exposure significantly. Additional specific measures should be considered, e.g. specific information of workers, use of wet cleaning practices, if possible with water mist conditions, and others. In general, it is also recommended to enclose the work post where bagging occurs. Occasional spills at the bagging installation should always be cleaned up immediately to avoid further contamination of the area.

In addition, the use of personal protective equipment is considered necessary (proper respiratory protection devices, see contributing scenario 9.1.1.2.), as long as further measurements have not demonstrated that the workplace air exposure is compliant with the DNELs.

Table 6c. Monitored data for workers specifically taken at the “bagging” operations.

element	Respirable fraction (µg/m3)	Inhalable fraction (µg/m3)	DNEL respirable (µg/m3)	DNEL inhalable (µg/m3)	RCR
As	na	111		10	11.1
Cd	0.99	na	4		0.25
ZnO	na	2311		5000	0.46
Cu	na	248		200	0.70
Mn	na	44		200	0.13
Pb	na	2802		150	7.9

Discussion

As indicated, monitored data are used by preference for assessing worker exposure, since they reflect reality. For this scenario, relevant monitoring data are available for the typical jobs/tasks that are performed by the workers. In this assessment, the focus is put on the potential local inhalation effects of the metals contained in the substance that are considered most critical in a workplace situation. The observed monitored exposure levels of the workers for the different job descriptions are well below DNELs or occupational exposure limit values for the metals in tables 6a and 6b (Zn: 2000 µg/m3, Pb: 50 µg/m3, and Cd: 10 µg/m3 and 4 µg/m3 for inhalable and respirable, respectively). Also, when considering combined exposure from the different metals present by summing up risk ratios, no risk is predicted.

Special attention should be paid to “bagging” operations where potential for exposure is higher and where additional risk management measures should be installed to bring the exposure down to acceptable levels.

Given that the availability of good quality, recent monitoring data available for the different job descriptions of this scenario, exposure modelling is not performed.

Conclusion

Based on the monitoring data relevant for the different jobs/tasks of this scenario, it can be concluded that no risk is predicted for the workers active in this scenario, when the risk management measures as described in this scenario are applied.

The exposure assessment above focuses on inhalation exposure. Dermal contact with substances at the workplace is linked to workplace air levels (contact through deposition from air, and contact with contaminated surfaces). Direct contact (through e.g. immersion) is not relevant.

Dermal exposures to the metals involved, as estimated with the MEASE model (use of properly designed gloves assumed), are all very low, i.e. ≤ 0.0005 mg/d (= MEASE-estimation of <0.24 mg/d, considering dermal absorption of 0.2% for dust). Based on these estimations, no risks are predicted for dermal effects, neither. It is emphasised that workers constantly wear protective clothing, including special gloves.

The proposed risk reduction measures will also reduce the possible exposure to other metals e.g. Cr, Cu, Sb, Al and Mn.

1.3. Exposure scenario 3: Use of the intermediate

Full title: Industrial use of the isolated Intermediate Leach Pb residue (293-314-4), in the ultimate manufacturing of Lead or Lead compounds by pyro-metallurgical processes

Table 3. Exposure scenario 3 for the intermediate Pb-leach residue

Exposure Scenario Format (1) addressing uses carried out by workers
Title of Exposure Scenario Leach Pb residue - 3: Industrial use of the isolated Intermediate Leach Pb residue (293-314-4), in the ultimate manufacturing of Lead or Lead compounds by pyro-metallurgical processes.
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant; SU: 8, 14 PROC: 2, 3, 8b, 9, 13, 22, 26 PC: 19 AC: not applicable ERC: 6a
Further explanations (if needed) The 'Leach Pb residue' (293-314-4) is unloaded, blended with other, primary and/or secondary materials, and loaded in Smelting Furnaces (ISA, Blast, ...) or similar for further smelting and extraction of Lead metal or Lead compounds.
Exposure Scenario
1.3.1 Contributing scenario (1) controlling environmental exposure for the Industrial use of the isolated Intermediate Leach Pb residue (293-314-4), in the ultimate manufacturing of Lead or Lead compounds by pyro-metallurgical processes.
Further specification: • The 'Leach Pb residue' is unloaded from transport trucks, ADR-big-bags or containers, …and transferred to storage silo's through especially designed transfer units, • The 'Leach Pb residue' is optionally blended with other Lead-containing primary or secondary materials • The mixture is continuously fed to smelting furnaces (i.e. ISA, Blast, ...) • The 'Leach Pb residue' is typically used in the production of Lead metal (EC 231-100-4) and recovery of precious metals. Maintenance activities
Product characteristics
Product related conditions: The 'Leach Pb residue' is a lumpy wet filtercake with an average Lead-content of 20-70% w/w The Lead melt produced contains up to >90%w/w Lead
Amounts used
Daily and annual amount per site:

maximum 50000 T/y of Lead contained

Frequency and duration of use

Continuous production

Environment factors not influenced by risk management

Flow rate of receiving surface water:

Default is used unless specified otherwise

Other given operational conditions affecting environmental exposure

Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process (via air and waste water); dry or water based processes; conditions related to temperature and pressure; indoor or outdoor use of products; work in confined area or open air;

Blending, and optionally pelletizing, and furnaces are operated under strong aspiration (negative pressure towards atmospheric pressure)

An appropriate (process) gascleaning system is applied

- Besides process waters, some non-process waters can be generated containing zinc (e.g. from cleaning)
- All processes are performed in a confined area. All residues containing zinc are recycled.

Technical conditions and measures at process level (source) to prevent release

Process design aiming to prevent releases and hence exposure to the environment; this includes in particular conditions ensuring rigorous containment; performance of the containment to be specified (e.g. by quantification of a release factor in section 9.x.2 of the CSR);

- Process enclosures and closed circuits where relevant and possible.
- Containment of liquid volumes in sumps to collect/prevent accidental spillage, acid solutions are treated appropriately.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; specify effectiveness of measures;
specify the size of industrial sewage treatment plant (m3/d), degradation effectiveness and sludge treatment (if applicable);

- On-site waste water treatment techniques can be applied to prevent releases to water (if applicable) e.g.: chemical precipitation, sedimentation and filtration (efficiency 90-99.98%).
- Containment of liquid volumes in sumps to collect/prevent accidental spillage
- Air emissions are controlled by use of cyclones, scrubbers, filters, demisters and/or other air emission abatement devices e.g. filters (up to 95% efficiency), wet scrubbers (50-95% efficiency). This may create a general negative pressure at the system openings (loading, sampling, production exit).

Organizational measures to prevent/limit release from site

Specific organisational measures or measures needed to support the functioning of particular technical measures.

- In general, emissions are controlled and prevented by implementing an integrated

management system e.g. ISO 9000, ISO 14000 series, or alike, and, when applicable, by being IPPC-compliant (cf. NFM-BREF).

Such management system, should include general industrial practice like e.g.:

- The substance/ UVCB is rigorously contained by technical means during the whole lifecycle including manufacture, purification, cleaning/maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
- Procedural and control technologies shall be used that minimise emission and any resulting exposure
- Only properly trained and authorised personnel handles the substance
- For cleaning/maintenance, special procedures such as system purging and washing before opening devices
- Procedures, control technologies for accidents and waste
- Substance-handling procedures well documented and strictly supervised

- Treatment and monitoring of releases to outside air, and exhaust gas streams (process & hygiene), according to national regulation.
- SEVESO 2 compliance, if applicable

Conditions and measures related to municipal sewage treatment plant

Size of municipal sewage system/treatment plant (m3/d); specify degradation effectiveness; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable); please note*: the default size of the municipal STP (2000 m_3/d) will be rarely changeable for downstream uses.*

In cases where applicable: default size, unless specified otherwise.

Conditions and measures related to external treatment of waste for disposal

Fraction of used amount transferred to external waste treatment for disposal; type of suitable treatment for waste generated by workers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste; specify effectiveness of treatment;

- If any, all hazardous wastes are treated by certified contractors according to EU and national legislation.

Conditions and measures related to external recovery of waste

Fraction of used amount transferred to external waste treatment for recovery: specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery out-side waste incinerators; specify effectiveness of measure;

- All residues formed during the smelting process, are recovered and either further treated in the system or handled according the waste legislation.

- Users of Zn/Pb and Zn/Pb-compounds have to favour the recycling channels of the end-of-life products
- Users of Zn/Pb and Zn/Pb-compounds have to minimize Zn/Pb-containing waste, promote recycling routes and, for the remaining, dispose the waste streams according the Waste regulation.

1.3.2 Contributing scenario (3) controlling worker exposure for the Industrial use of the isolated Intermediate Leach.Pb.residue (293-314-4), in the ultimate manufacturing of Lead or Lead compounds by pyro-metallurgical processes.

Name of contributing scenario 3:

The 'Leach Pb residue' (293-314-4) is unloaded, blended with other, primary and/or secondary materials, and loaded in Smelting Furnaces (ISA, Blast, ...) or similar for further smelting and extraction of Lead metal or Lead compounds.

Further specification

Product characteristic

Product related conditions, e.g. the concentration of the substance in a mixture, the physical state of that mixture (solid, liquid; if solid: level of dustiness), package design affecting exposure)

- The treated substance/ UVCB is lumpy wet cake,
- Besides the metal phase produced (rough Pb metal), slag is also cast and further processed
- With occasional (sampling, cleaning, maintenance) and potentially direct exposure for workers
- The average Pb content of the melt lies above 90% w/w and needs further refining steps (distillation columns)
- Cadmium compounds (up to 1% w/w Cd) and other NF-Metals are potentially present

Amounts used

Amounts used at a workplace (per task or per shift); note: sometimes this information is not needed for assessment of worker's expo-sure

Maximum 300 T/day, 100T/shift of Lead contained

Frequency and duration of use/exposure

Duration per task/activity (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure

8hrs shift

Human factors not influenced by risk management

Particular conditions of use, e.g. body parts potentially exposed as a result of the nature of the activity

Uncovered body parts: (potentially) face

Other given operational conditions affecting workers exposure

Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process into workers environment; room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature and pressure.

- All processes are carried out in confined areas with a minimum of operators
- The process is managed and controlled from a separate control-room.

Technical conditions and measures at process level (source) to prevent release

Process design aiming to prevent releases and hence exposure of workers; this in particular includes conditions ensuring rigorous containment; performance of containment to be specified (e.g. by quantification of residual losses or exposure)

- Local exhaust ventilation on work areas with potential dust generation, dust capturing and removal techniques
- Process enclosures closed circuits or semi-enclosures where appropriate.
- Containment of liquid volumes in sumps to collect/prevent accidental spillage

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

Engineering controls, e.g. exhaust ventilation, general ventilation; specify effectiveness of measure

- Local exhaust ventilation systems (generic LEV (84%)),
- Cyclones/scrubbers/ demisters (for minimizing air emissions): efficiency: 70-90% (cyclones), 50-80% (dust filters), 85-95% (Scrubbers, Absorbers...)
- Dust control: dust and Zn in dust needs to be measured in the workplace air (static or individual) according to national regulations.
- Special care for the general establishment and maintenance of a clean working environment by e.g.:
    - Cleaning of process equipment and workshop
    - Storage of calcine/sinter in dedicated silos and solutions in covered vessels and thickeners

Organisational measures to prevent /limit releases, dispersion and exposure

Specific organisational measures or measures needed to support the functioning of particular technical measures (e.g. training and supervision).

- In general, an integrated management system is implemented on the workplace e.g. ISO 9000, ISO ICS-13100 series, or alike, and, when applicable, by being IPPC-compliant

  Such management system, should include general industrial practice like e.g.:
    - The substance/ UVCB is rigorously contained by technical means during the whole lifecycle including manufacture, purification, cleaning/maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
    - Procedural and control technologies shall be used that minimise emission and

any resulting exposure

- Only properly trained and authorised personnel handles the substance
- For cleaning/maintenance, special procedures such as system purging and washing before opening devices
- Procedures, control technologies for accidents and waste
- Substance-handling procedures well documented and strictly supervised

- Additionally, in case of need, personal protection measures (see below)

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

Personal protection, e.g. wearing of gloves, face protection, full body dermal protection, goggles, respirator; specify effectiveness of measure; specify the suitable material for the PPE (where relevant) and advise how long the protective equipment can be used before replacement (if relevant)

Wearing of gloves and protective clothing is compulsory (efficiency >=90%).

With normal handling, no respiratory personal protection (breathing apparatus) is necessary. If risk for exceedance of OEL/DNEL, use e.g.:

-dust filter-half mask P1 (efficiency 75%)

-dust filter-half mask P2 (efficiency 90%)

-dust filter-half mask P3 (efficiency 95%)

-dust filter-full mask P1 (efficiency 75%)

-dust filter-full mask P2 (efficiency 90 %)

-dust filter-full mask P3 (efficiency 97.5%)

Eyes: safety glasses are recommended

Exposure assessment

A. Workers

At the receiver's end (user of the intermediate-exposure scenario 2), the extensive available individual monitoring data are grouped together in two "intermediate workplace" situations: "materials handling process" (54 workers in total) and "smelter process" (51 workers in total). For these 2 workplace situations, an assessment is done for given work situations as specified in the table below. For each of these situations, more than 6 measurements are available.

Technical specifications of the monitoring:

All measurements were performed by personal sampler (unless indicated otherwise), during the period 2010-2013.

-sampling device: Buck VSS-5 Validated System,

-flow rate : 2000cc/min (Volume aspired ranged between 650 l and 860 l; duration of sampling was ~=360 minutes (range: 325-430);

-filter type : IOM sampler equipped with a PVC cassette (all inhalable fraction)

-method of analysis: Microgolf dissolution in HCl/HNO3/HF + ICP-OES analysis

For the human health assessment of the intermediate, the metals contained in table below are considered relevant. See also table 2.

Results are given in table below.

Table 4. Monitored metal concentrations in workplace air (50P/90P inhalable fraction in µg/m3; values indicated as "<x" were taken as "x") at the user plant. The original data are available from IZA.

Metal in workplace air (µg/m3)	Number of workers	Arsenic	cadmium	cobalt	Copper	Lead	nickel	zinc
materials handling process								
Forklift driver	15	1.8/2.1	0.28/0.38	0.28/0.28	8.3/13.8	11.9/19.1	2.8/2.8	1.5/7.5
Wheelloader driver	31	1.8/1.8	0.5/0.8	0.28/0.28	5.8/13.5	12.9/18.9	0.28/0.28	4.1/13.7
Fixed place forklift*	5	1.8/1.8	0.28/0.28	0.28/0.28	2.8/4.3	4.9/6.6	0.28/0.28	1.4/1.4
smelter process								
Crane driver	20	1.8/6.9	0.6/1.8	0.28/0.28	5.3/22.0	8.7/54.6 **75P: 31.7**	2.8/2.8	1.9/12.2
Worker slag casting	29	1.9/6.3	0.62/4.3	0.28/0.28	7.2/54.5	12.8/70.5 **75P: 41.2**	2.8/2.8	2.1/11.7
Controller furnace top	31	1.8/1.8	0.28/1.36	0.28/0.28	3.0/8.8	8.3/18.3	2.8/2.8	1.4/2.8
Control room fixed place*	31	1.8/1.8	0.28/0.36	0.28/0.28	2.8/3.3	5.9/8.86	2.8/2.8	1.4/1.8

Wheelloader driver	31	1.8/2.0	0.62/1.78	0.28/0.28	5.1/9.8	12.3/40.8	2.8/2.8	2.8/6.5
Worker dayshift	38	1.8/2.1	0.49/0.94	0.28/0.28	5.1/9.2	9.2/14.9	2.8/2.8	1.5/4.5
Worker Cu casting	27	1.8/4.4	0.28/1.74	0.28/0.28	3.9/25.1	6.5/33.4	2.8/2.8	1.4/7.0
DNEL inhalation local (**mg/m3**)		0.01-0.05 (inhal) OEL	0.004(resp)		1	0.05-0.15 (inhal) OEL	0.05	5(slightly sol); 1.25 (soluble)
Risk ratio range (90P)		0.18-0.69	0.036-0.43**		0.0033-0.055	0.044-1.41	0.056	0.00036-0.011
Risk ratio range (75P)						**0.21-0.82**		
Risk ratio range (50P)		0.036-0.19	0.028-0.064**		0.0028-0.0072	0.0033-0.26	0.0056	0.00028-0.0033

*static sampling
** considering a factor inhalable-respirable of 2.5

Discussion

The monitoring data demonstrate that the different metals contained in the intermediate are not the cause of risk for local inhalatory effects, which is considered to be the most sensitive endpoint in the workers situation. Risk ratios for local inhalation effect are <1, due to risk management measures applied and the wet nature of the processes involved. The one exemption to this general picture is Pb where for some activities the combination of the 90P worst case exposure with the lowest OEL gives a risk ratio between 1 and 1.4. In this respect it is emphasised that a) Pb exposure is bio-monitored continuously by measuring Pb in blood, and b) personal respiratory protection is always mandatory in exceptional cases where there is possibility for increased exposure. The protective effect of such personal protection measures is not taken into account in the workplace air monitoring.

Moreover, according to ECHA guidance R14, 90P values are used for the assessment above. The same guidance allows to use the P75 if the exposure data set is well defined, of high quality, referring to homogenous exposure conditions (which is the case for company specific assessments), and results in a risk ratio clearly below 1 and being fully representative for the operational conditions and risk management measures described in the exposure

scenario. These criteria are all fulfilled in the present case; based on the 75P, a risk ratio<1 can thus also be considered for the 2 activities resulting in a higher P90 for Pb.

The metal concentrations in this workplace are resulting from different activities and substances, i.e. different intermediate UVCBs. The measured metal concentrations are thus not related to the intermediate under study alone, and are, consequently, an overestimation.

Taking all the above into account, it can be concluded from this quantitative assessment that no inhalation risk is predicted when the risk management measures as indicated in the exposure scenario are applied.

Dermal contact with substances at the workplace is linked to workplace air levels (contact through deposition from air, and contact with contaminated surfaces). Direct contact (through e.g. immersion) is not relevant.

There are no direct data on dermal exposure. For the metals Pb, Cd and As, dermal exposure is integrated in the biomonitoring for these substances that is routinely performed at the plants. More importantly, it is noted that workplace concentrations of As and Cd are very low, as follows from table above. For the metal present in more significant levels, i.e. Pb, it is known that Pb is most easily taken up by inhalation or ingestion, and that dermal uptake is negligible in terms of systemic uptake, as compared to the other routes of exposure. So, according to the qualitative assessment, considering the elements above in combination with the very low exposure levels in the workplace air, no risks are predicted for dermal effects, neither. It is emphasised that workers constantly wear protective clothing, including special gloves.

B. Environment

For the environmental assessment of the intermediate, the metals contained in tables below are considered relevant. See also table 2.

Air emisions and soil risk characterisation

The emissions of metals to air are measured at two relevant stacks throughout the year, once a month. The average and 90P value for the year 2012 are given in table below.

The contribution of the emissions to the local PEC soil (regional PEC + local added concentration) were calculated for the metals zinc and cadmium. It is clear that at the observed level of emission, the contribution of the plant's emissions to the local soil PEC is minimal. The local PEC and related risk ratio is for the greater part related to the regional background.

Table 5.. Emission of metals to air, and risk characterisation for local soil.

Emissions	Cu	Pb	As	Zn	Cd	Sb

mg/d						
average	10633.16	24543.19	12442.58	4389.618	4102.845	2785.014
90p	19634.13	37339.62	25971.93	14656.1	6350.479	5863.346
PNECsoil mg/kg_{dw}	88	147	0.3	107	0.9	
Risk ratio			0.005**	0.39*	0.82*	

*At the given emission levels, the actual emissions contribute only marginaly to the soil exposure and risk ratio; the calculated risk ratio is entirely due to the regional background.
** risk ratio calculated on local input only

In conclusion: the contribution of emissions of relevant metals to air to the local PEC and risk ratio for (local) soil is minimal.

Water emissions and aquatic risk characterisation:

Metal levels in effluent water from the site (collecting process waters and surface run-off waters) were measured daily. Waste waters were first treated by sedimentation, followed by chemical purification. In table below, the results taken over the year (2012) are averaged, and the 90P, and 50P values are calculated, resp.

Table 6: Emissions of metals to water, resulting concentration in the receiving water and risk characterisation.

metal	Cu	Pb	Ni	As	Zn	Cd
concentration in the effluent waters (mg/l)						
average	0,013455	0,01925	0,038667	0,16775	0,016455	0,009182
90p	0,024	0,0239	0,0509	0,218	0,023	0,016
50p	0,009	0,0115	0,039	0,1735	0,014	0,008
Concentration in the receiving water (PEC in µg/l)*						
average	0,003041	0,004351	0,00874	0,037918	0,003719	0,002075
90p	0,005425	0,005402	0,011505	0,049277	0,005199	0,003617
50p	0,002034	0,002599	0,008816	0,039218	0,003165	0,001808
PNEC (µg/l)	7,8	6,5	3,55	6,5	20,6	0,19
Risk ratios PEC/PNECfreshwater						
average	0,00039	0,000669	0,002462	0,005834	0,000181	0,010923
90p	0,000696	0,000831	0,003241	0,007581	0,000252	0,019035

50p	0,000261	0,0004	0,002483	0,006034	0,000154	0,009517
Risk ratios PEC/PNECfreshwater sediment						
90p					0.75	0.37**

*Calculated with a discharge flow of 2813m3/d; flow of receiving water: 12441600m3/d
**At the given emission level, the actual contribution of the emissions to the water exposure and the risk ratio is rather limited; the calculated risk ratio is mainly due to the regional background.

Discussion:
Based on the extensive monitored data, it can be concluded that for none of the main relevant metals, a risk is calculated for the water. When all risk ratios of the metals presented in table above are summed up, the sum is never near to 1 (sum of risk ratios based on average emission: 0.021; sum of risk ratios based on 90P values:0.032; based on 50P values: 0.019);
For the sediment, it is noted that no correction is done for bioavailability of Cd.

The endpoints STP (no emissions to STP), and marine waters/sediments (not located on coastal areas) are not relevant for the plant of this assessment.

Further considerations

Regional assessment
The data presented above demonstrate that the emissions related to the production and the use of the intermediate are very limited. Moreover, since the lifecycle of the intermediates is limited to their production and full use in industrial process, and since there are no downstream uses or wide dispersive consumer uses, the industrial releases to the environment are considered very limited, and insignificant for regional exposure/risk.

Man via the environment
Due to the limited emissions of the metals related to the production and use of the intermediate, and taking into account its short lifecycle, with production and use in only a small number of industrial sites in the EU, and, moreover, since there are no downstream or wide dispersive uses that may lead to significant further exposure through the environment, it is considered that the exposure to the metals contained in the intermediate via the environment is insignificant. The assessment of the exposure to the different metals is made in the respective chemical safety reports.