

<u>Grade name:</u> Lead metal massives (high purity grade) [particle diameter ≥1mm]

 Substance:
 Lead

 EC Number:
 231-100-4

 CAS Number:
 7439-92-1

Substance Type: Mono-constituent substance

Degree of purity: 99.9% (w/w)

Composition:

Constituent	Typical concentration	Concentration range	Remarks
lead EC no.: 231-100-4	99.9 % (w/w)	≥ 99.8 — ≤ 99.999 % (w/w)	
Impurity	Typical concentration	Concentration range	Remarks
Different metal impurities not affecting classification of substance		≥ 0.0 — ≤ 0.2 % (w/w)	Metal impurities in the range <0.2% (w/w): e.g. Sb, Sn, Cu, Al, Zn, Fe, Cr, Se, Mg, Mn, Na, Ba, Sr, In, Ga, Te, Ag, Bi, Au, Ca, Pt; metal impurities in the range <0.1% (w/w): Ni, Tl; metal impurities in the range <0.025% (w/w): As, Cd, Hg;; metal impurities in the range <0.01% (w/w): Co.

HARMONISED CLASSIFICATION IN ACCORDANCE WITH THE CLASSIFICATION LABELLING AND PACKAGING REGULATION EC (NO) 1272/2008

Repr. 1A; H360FD; May damage fertility. May damage the unborn child.

Lact.: H362; May cause harm to breast-fed children.

Aquatic Chronic 1: H410; Very toxic to aquatic life with long lasting effects.

INDUSTRY SELF-CLASSIFICATION*

Repr. 1A; H360FD: May damage fertility. May damage the unborn child.

Lact.; H362: May cause harm to breast-fed children.

STOT RE1; H372: Causes damage to organs through prolonged or repeated exposure.

Aquatic Chronic 1: H410; Very toxic to aquatic life with long lasting effects.

Specific Concentration Limits, M-Factors:

M-Factor:

Aquatic Chronic 1; 10

Hazard pictograms:

GHS08: health hazard







Hazard statements:

H360FD: May damage fertility. May damage the unborn child.

H362: May cause harm to breast-fed children.

H372: Causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion.

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

Notes:

Industry self-classification explanation

Lead metal massive (high purity grade) is included in Annex VI, Table 3.1 of Commission Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, under the entry "lead massive: [particle diameter ≥ 1 mm]" (Index No 082-014-00-7), agreed in the 9th ATP to CLP. As such this entry is legally binding and must be cited on both the label and SDS. The entry was updated to include Aquatic Chronic 1 by Commission Delegated Regulation (EU) 2024/197, published on 19 October 2024; this harmonised environmental classification is similarly legally binding across the European Union from 1 September 2025.

The toxicity of lead is generally considered to be mediated through the lead cation; it is manifested in effects on reproductive function but also on other body systems (blood, kidneys, reproductive function, development and the central nervous system).

In line with Art. 5(1) of CLP, classification must be based on the form the substance is placed on the market and how it is reasonably expected to be used. Although metallic lead is considered to have a low dermal absorption rate, lead oxide formed on the surface of lead can rub off on the skin becoming systemically available by hand to mouth contact. Lead metal may also be used in such a way that inhalable particles may form, resulting in systemic uptake as is the case with lead powder.

Given the systemic availability of the lead ion from metallic lead (which was used to justify the CLH entry), STOT-RE1; H372 is applied in addition to the harmonised classification. No SCL was set for reproductive toxicity for the massive form, thus the GCL of 0.3% applies; similarly, for STOT-RE, no SCL is required.

The EU harmonised environmental classification of lead metal massive; [particle diameter ≥ 1 mm] as Aquatic Chronic 1 under Commission Delegated Regulation (EU) 2024/197, published on 19 October 2024, is legally binding across the European Union from 1 September 2025. An M-factor of 10 was assigned for chronic effects to the aquatic environment:

• Aquatic Chronic 1; M-factor = 10

No harmonised acute environmental classification was assigned for lead metal massive under Regulation (EU) 2024/197. Industry also concludes via self-classification that lead metal in massive form does not meet the criteria for acute aquatic classification.

Labelling derogation

A derogation from labelling requirements exists for metals in massive form. Such metals do not require a label according to Annex 1 to Regulation (EC) No 1272/2008 if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, although classified as hazardous in accordance with the criteria of that Annex.

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