



Lead REACH  
CONSORTIUM

**Grade name:** Lead metal massives (with arsenic grade) [particle diameter  $\geq 1\text{mm}$ ]  
**Substance:** Lead  
**EC Number:** 231-100-4  
**CAS Number:** 7439-92-1  
**Substance Type:** Mono-constituent substance  
**Degree of purity:** 95.0 % (w/w)

**Composition:**

Constituent	Typical concentration	Concentration range	Remarks
lead EC no.: 231-100-4	95.0 % (w/w)	$\geq 80.0 - \leq 100.0$ % (w/w)	
Impurity	Typical concentration	Concentration range	Remarks
tin EC no.: 231-141-8		$\geq 0.0 - \leq 15.0$ % (w/w)	
antimony EC no.: 231-146-5		$\geq 0.0 - \leq 15.0$ % (w/w)	
sulfur EC no.: 231-722-6		$\geq 0.0 - \leq 10.0$ % (w/w)	only in elemental form
oxygen EC no.: 231-956-9		$\geq 0.0 - \leq 10.0$ % (w/w)	only in elemental form
copper EC no.: 231-159-6		$\geq 0.0 - \leq 10.0$ % (w/w)	
aluminium EC no.: 231-072-3		$\geq 0.0 - \leq 10.0$ % (w/w)	
zinc EC no.: 231-175-3		$\geq 0.0 - \leq 10.0$ % (w/w)	
iron EC no.: 231-096-4		$\geq 0.0 - \leq 10.0$ % (w/w)	
Chromium EC no.: 231-157-5		$\geq 0.0 - \leq 10.0$ % (w/w)	
Manganese EC no.: 231-105-1		$\geq 0.0 - \leq 10.0$ % (w/w)	
sodium EC no.: 231-132-9		$\geq 0.0 - \leq 10.0$ % (w/w)	
Barium EC no.: 231-149-1		$\geq 0.0 - \leq 10.0$ % (w/w)	
strontium EC no.: 231-133-4		$\geq 0.0 - \leq 10.0$ % (w/w)	
Indium EC no.: 231-180-0		$\geq 0.0 - \leq 10.0$ % (w/w)	
gallium EC no.: 231-163-8		$\geq 0.0 - \leq 10.0$ % (w/w)	
tellurium EC no.: 236-813-4		$\geq 0.0 - \leq 10.0$ % (w/w)	
calcium EC no.: 231-179-5		$\geq 0.0 - \leq 10.0$ % (w/w)	
silicon EC no.: 231-130-8		$\geq 0.0 - \leq 10.0$ % (w/w)	

Constituent	Typical concentration	Concentration range	Remarks
Potassium EC no.: 231-119-8		≥ 0.0 — ≤ 10.0 % (w/w)	
Magnesium EC no.: 231-104-6		≥ 0.0 — ≤ 10.0	
arsenic EC no.: 231-148-6		≥ 0.0 — < 5.0 % (w/w)	Impurity is relevant for C&L of the substance.
selenium EC no.: 231-957-4		≥ 0.0 — ≤ 5.0 % (w/w)	
bismuth EC no.: 231-177-4		≥ 0.0 — ≤ 2.0 % (w/w)	
nickel EC no.: 231-111-4		≥ 0.0 — ≤ 1.0 % (w/w)	
cobalt EC no.: 231-158-0		<b>≥ 0.0 — &lt; 0.01 % (w/w)</b>	
Different metal impurities not affecting classification of substance		≥ 0.0 — ≤ 0.25 % (w/w)	Metal impurities in the range <0.25% (w/w): e.g. Pt, Ag, Au; metal impurities in the range <0.1% (w/w): Tl; metal impurities in the range <0.025% (w/w): Cd, Hg.

### **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.

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

***†Aquatic Chronic 2; H411: Toxic to aquatic life with long lasting effects (Note: Aquatic Chronic 2 applies only if [As] ≥ 2.5 %. Chronic 3 would apply when ≤ 0.25% [As] <2.5%)***

***†Carc. 1A; H350: May cause cancer***

### **CLP LABELLING**

Signal word: Danger

Hazard pictograms:

GHS08: health hazard



GHS09: environment

*(only required where concentration of Arsenic is ≥ 2.5 %*



Hazard statements:

H350: May cause cancer

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.

H411: Toxic to aquatic life with long lasting effects

*(applies only if [As] ≥ 2.5 %. Chronic 3 (H412) would apply when ≤ 0.25% [As] <2.5%).*

***†Industry self classification***

**Notes:****Industry self-classification explanation†**

Lead metal massives (with arsenic grade) [particle diameter  $\geq 1\text{mm}$ ] is included in Regulation (EC) No 1272/2008 Annex VI Table 3.1 under the entry “lead massive: [particle diameter  $\geq 1\text{mm}$ ]” (Index No 082-013-00-1), which was introduced by the 9<sup>th</sup> ATP to CLP. As such, this entry is legally binding and must therefore be cited on both the label\*\* and SDS from the date of application stated in the 9<sup>th</sup> ATP. However, for endpoints not covered by the Annex VI entry, the manufacturer, importer or downstream user is required to self-classify the substance in accordance with the CLP Regulation.

The lead cation is generally accepted to be the primary mediator of lead toxicity, which is manifested in effects on blood, kidneys, the central nervous system, development, and reproductive function. Therefore, “STOT RE1; H372: Causes damage to organs through prolonged or repeated exposure” is assigned to lead metal massives (with arsenic grade) [particle diameter  $\geq 1\text{mm}$ ] due to systemic availability of the lead cation.

Due to differences in relative bioavailability between powder and massive forms, it is recommended to use the generic concentration limit of 10% for STOT-RE1 for lead metal massives (with arsenic grade) [particle diameter  $\geq 1\text{mm}$ ].

Self-classification for arsenic as Carc. 1A was introduced by the Arsenic Consortium in February 2018. Accordingly, the boundary composition for "lead metal massives (with arsenic)" is classified as Carc. 1A. This classification arises solely from the Arsenic content of the boundary composition being above the GCL of 0.1%; it only applies to this registered grade of Pb metal.

Additionally, to bring the classification into line with the latest scientific data and knowledge, industry proposes “Aquatic Chronic 2; H411: Toxic to aquatic life with long lasting effects” where the concentration of the arsenic is  $\geq 2.5\%$ . Previously, lead metal massives (with arsenic grade) [particle diameter  $\geq 1\text{mm}$ ] was classified conservatively for environmental effects as “Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects” and “Aquatic Acute 1; H400: Very toxic to aquatic life” due to the absence of TDp testing on this particular grade. The new proposed classification uses a read-across approach from available TDp data for lead metal massives (high purity grade; 99.9% Pb). The presence of arsenic is not expected to increase the release of soluble lead ions from the massive form. The new proposed environmental classification is also aligned with the results of the current Tier 1 MECLAS classification for the composition provided above.

\*\* 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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