Lead Metal and the 9th ATP to CLP: Frequently Asked Questions

Commission Regulation (EU) 2016/1179 – commonly known as the 9th ATP to CLP – was published in the Official Journal of the European Union on 20 July 2016. This Adaptation to Technical Progress introduces harmonised health classification for lead metal, as agreed unanimously by the REACH Article 133 Committee in February 2016. The harmonised classification is split into two entries, one for lead powder and one for massive forms.

This document has been prepared to address common questions about the impact of the harmonised classification for lead metal. However, if you have a question that is not covered here, please contact the Secretariat (reach@ila-lead.org).

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1. What is the harmonised classification for lead metal introduced by the 9th ATP?

The 9th ATP to CLP introduces two harmonised classification and labelling (CLH) entries for lead metal, which are added to Table 3.1 of Part 3 of Annex VI. One entry applies to lead metal in powder form (particle diameter <1mm; Index No 082-013-00-1) and one to lead metal massive (particle diameter ≥1mm; 082-014-00-7), as presented in **Table 1**.

The same hazard classes and categories, hazard statements, pictograms and signal words apply to both forms of lead metal; however, the powder form has been assigned a Specific Concentration Limit (SCL) of ≥0.03% for effects on development.

Table 1 CLH entries for lead metal

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
082-013-00-1	lead powder; [particle diameter < 1 mm]	231-100-4	7439-92-1	Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362		Repr. 1A; H360D: C ≥ 0,03 %
082-014-00-7	lead massive: [particle diameter ≥ 1 mm]	231-100-4	7439-92-1	Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362		

2. Why are lead powder and lead massive listed separately in the 9th ATP to CLP?

After a very effective advocacy campaign conducted by a cross-metal commodity task force of Eurometaux, Industry was able to secure a decision such that lead massive is treated differently to lead powder: for lead massive, the generic concentration limit (GCL) of ≥0.3% applies, whereas the specific concentration limit of ≥0.03% applies for lead powder. Recital 4 of the 9th ATP to CLP refers to differences in bioavailability as the rationale for this differentiation.

The distinction between the two forms of lead metal is important as it reduces the impact of the lead classification on classification and labelling of other metals and metal mixtures in massive form containing trace amounts of lead. The decision to treat lead powder and lead massive separately based upon relative bioavailability also supports the continued development and validation of the bioelution test protocol, which is important for refining classification of metal mixtures based upon bioaccessibility of a metal rather than content. By measuring the extent to which a test substance is released in synthetic biological fluids, bioelution testing provides a conservative estimate of bioavailability. In the case of lead, bioelution data has indicated that the bioaccessibility of Pb ions from lead massive is 10-100 times lower than that from lead powder; therefore, the concentration limit for lead powder (≥0.03%) is increased for lead massive by a factor of 10, i.e. to ≥0.3%.

3. What does the Specific Concentration Limit of ≥0.03% mean, and does this apply to both fertility and concerns about the unborn child?

The Specific Concentration Limit (SCL) of ≥0.03% applies to lead powder (particle diameter <1mm), not to lead in massive form. The SCL applies only to effects on development; the generic concentration limit of ≥0.3% applies for effects on fertility and effects via lactation.

The SCL introduced by the 9th ATP to CLP means that mixtures in powder form which contain 0.03% or more lead must be classified as Repr. 1A; H360D; at higher concentrations (0.3% and above), classification for effects on fertility and via lactation also applies.

4. Does the classification mean that the risks from lead metal have changed? Should it be handled differently now?

No. Classification reflects the intrinsic properties of a material; it is not a statement about the risk posed during use. A risk assessment, whether undertaken as part of the REACH registration or by employers under the provisions of workplace legislation, considers the intrinsic properties of a material and the potential for exposure during its use. The assessment also takes into consideration existing risk management measures to ensure the protection of workers and the environment.

The properties of lead, including its effects on fertility and development, are not new. Comprehensive EU legislation is already in place to reduce risks to human health and the environment, supplemented by voluntary Industry initiatives such as worker blood lead reduction programs.

Existing workplace measures in connection with the handling and use of lead, including those under the Chemical Agents and Pregnant Workers Directives (98/24/EC and 92/85/EEC), remain in effect.

5. Where can I find the Industry classification and labelling information for lead metal?

The 9th ATP to CLP provides the legally binding harmonised classification for lead metal. However, for endpoints not covered by the Annex VI entry, the manufacturer, importer or downstream user is required to classify the substance in accordance with the CLP Regulation.

The latest substance grade data sheets showing the Industry classification are available on the Consortium's website and are also available on request from the Secretariat. The Lead REACH Consortium SDS templates have been updated, and the Industry classification was first submitted in a dossier update by the Lead Registrant for lead metal in June 2016.

The lead cation is the primary mediator of lead toxicity, which is manifested in effects on blood, kidneys, the central nervous system, development, and reproductive function following repeated exposure. Therefore, in addition to the harmonised classification, Industry has assigned "STOT RE1; H372: Causes damage to organs through prolonged or repeated exposure" to lead metal. However, due to differences in relative bioavailability, separate concentration limits apply to the different forms:

- lead metal powder: specific concentration limit of ≥0.5%
- lead metal massive: generic concentration limit of 10%.

Table 2 provides a summary of the health classification and labelling for lead-containing materials, based on lead content. It should be noted that the table does not cover environmental classification, which is at present relevant for lead powder and the 'lead massive with arsenic' grade.

Table 2 Summary of SDS obligations, health classification and label elements

Material	Lead content (w/w)	Health classification	Label elements – health	SDS mandated?
Architectural lead sheet; other lead-containing articles	Any	Not applicable	Not applicable	No
lead massive* [particle diameter ≥ 1 mm]	C ≥ 10%	Repr. 1A; H360FD Lact.; H362 STOT RE1; H372	 Danger 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	Yes
	0.3% ≤ C < 10%	Repr. 1A; H360FD Lact.; H362	 Danger H360FD: May damage fertility. May damage the unborn child H362: May cause harm to breast-fed children	Yes
	C < 0.3%	None	None	On request of recipient
lead powder**; [particle diameter < 1 mm]	C ≥ 0.5%	Repr. 1A; H360FD Lact.; H362 STOT RE 1; H372	 Danger 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.	Yes
	0.3% ≤ C < 0.5%	Repr. 1A; H360FD Lact.; H362	 Danger H360FD: May damage fertility. May damage the unborn child H362: May cause harm to breast-fed children	Yes
	0.03% ≤ C < 0.3%	Repr. 1A; H360D	 Danger H360D: May damage the unborn child	Yes
	C < 0.03%	None	None	On request of recipient

** Environmental classification also applies only to the grade 'lead massive with arsenic'*

*** Environmental classification also applies to this form. See substance grade data sheets for more information.*

6. Why does Industry's self-classification go beyond the Annex VI entry introduced by the 9th ATP to CLP?

The classification of a substance as carcinogenic, mutagenic, or toxic for reproduction, or as a respiratory sensitiser, is harmonised and made obligatory at Community level through its entry in Annex VI to CLP. However, for other endpoints which are not covered by the Annex VI entry, the manufacturer, importer or downstream user is required to self-classify in accordance with CLP.

The 9th ATP to CLP provides the legally binding, harmonised classification for lead metal in light of its reproductive toxicity, i.e. its effects on development and fertility. However, following repeated exposure, lead toxicity also manifests as effects on blood, kidneys, and the central nervous system. Due to such 'specific target organ toxicity', mediated by the systemic availability of the lead ion in the body, Industry has assigned "STOT RE1; H372: Causes damage to organs through prolonged or repeated exposure" to lead metal. This self-classification applies in addition to the harmonised reproductive toxicity classification in the Annex VI entry.

7. As the classification for lead massive has changed, are safety data sheets required?

According to REACH Article 31(1)(a), a safety data sheet (SDS) is required for substances and mixtures meeting the criteria for classification as hazardous in accordance with the CLP regulation. Therefore, a SDS must be provided for:

- all lead metal grades in massive form, including ingots;
- alloys and other mixtures in massive form which contain ≥ 0.3% lead;
- lead powder; and
- mixtures in powder form which contain ≥ 0.03% lead.

The SDS must be provided proactively, not on request, at least at the time of first supply of the hazardous material, and to all former recipients supplied within the preceding 12 months. The latter also applies when the SDS is subsequently updated.

Additionally, since lead has Community workplace exposure limits, suppliers of mixtures containing lead *below* the relevant concentration limit specified above must provide a SDS to recipients on request. However, due to the existing occupational exposure limit values for lead, it is recommended to issue the SDS proactively.

The SDS must be provided free of charge, on paper or electronically, in an official language of the Member State where the substance or mixture is placed on the market, unless that Member State provides otherwise.

SDS are not required for articles as defined by REACH Article 3(3), for example architectural lead sheet; however, suppliers may provide their handling instructions in the format of the SDS. ELSIA, the European Lead Sheet Industry Association, provides such a template for its members to use.

8. Is it necessary to label lead ingots and lead in other massive forms?

Articles are not subject to classification and labelling requirements of CLP. Therefore, finished and semi-finished products such as lead sheet, ammunition, and lead pipes do not require CLP labelling.

CLP labels are also not normally required for substances or mixtures which are supplied without packaging: according to Article 17 of CLP, *"A substance or mixture classified as hazardous and contained in packaging shall bear a label … "*. Thus, unpackaged lead in massive form should not need a label.

In situations where packaging is used to supply lead in massive form, labelling is required unless the derogation provided by Article 23 and Section 1.3.4.1 of Annex I to CLP applies:

"*1.3.4.1. Metals in massive form, alloys,* […] *do not require a label according to this Annex, 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 this Annex.*

"1.3.4.2. Instead, the supplier shall provide the information to downstream users or distributors by means of the SDS."

When considering the derogation, it should be noted that, although metallic lead is considered to have a low dermal absorption rate, lead oxide formed on its surface can rub off on the skin, becoming systemically available by hand-to-mouth contact. Also, during some use patterns, inhalable particles may form, resulting in systemic uptake as is the case with lead powder.

Since 1 March 2018, suppliers must ensure that the packaging of lead supplied as a substance or in a mixture above the relevant concentration limits is marked visibly, legibly and indelibly as '**Restricted to professional users'**, before the products are placed on the market. Please see Qu. 14 for more information and the associated restriction on the supply to consumers.

9. When did the 9th ATP take effect?

The CLH entries introduced by the 9th ATP formally applied from 1 March 2018. However, suppliers could adopt the harmonised classifications voluntarily before that date.

In June 2016, the Lead Registrant for lead metal submitted a REACH registration dossier update to reflect the Industry classification, which incorporates the harmonised classification introduced by the 9th ATP. The Lead REACH Consortium SDS templates and substance grade data sheets for lead metal were also updated.

10. Does the 9th ATP affect the existing classification of lead compounds?

No. The two Annex VI entries for lead which are introduced by the 9th ATP apply only to lead as a substance and/or as a component of another substance or a mixture (i.e. a constituent or impurity). The existing harmonised classifications of the individually listed lead compounds, and those covered by the group entry 'lead compounds with the exception of those specified elsewhere in this Annex' (Index No 082-001-00-6), remain in place and unchanged.

11. Should lead massive be notified to the Classification and Labelling Inventory? **UPDATED**

As a hazardous substance, lead massive must be notified to the Classification and Labelling Inventory (CLI) by any EU/EEA importer or manufacturer who places the substance on the market on its own or in a mixture above the relevant concentration limit. A deadline of one month from placing on the market applies to the notification duty. However, classification and labelling information submitted by the Lead Registrant as part of a REACH joint submission constitutes notification by those registrants. The Lead Registration dossier was updated in June 2016 to recognise the new classification for lead massive; further dossier updates were submitted by the Lead Registrant during 2018.

12. Should lead massive, or lead alloys, be notified to national 'Poison Centres'?

Under the provisions of Article 45 of the CLP Regulation, there is a general reporting obligation at Member State level regarding hazardous mixtures, including alloys. This duty does not apply to articles such as lead sheet, nor to substances on their own such as pure lead ingots.

Importers and formulators of hazardous mixtures must provide information to appointed bodies (commonly known as Poison Centres) to assist medical professionals in the event of emergency health response, and to allow Member States to undertake statistical analysis to identify where improved risk management measures may be needed.

A similar provision existed under the former Dangerous Preparations Directive (1999/45/EC), reporting mechanisms already exist in many Member States. However, the approach was not harmonised, and the existing requirements could differ significantly between countries.

To standardise the approach across the EU/EEA, Commission Regulation (EU) 2017/542 was published in the Official Journal of the EU on 23 March 2017. From 1 January 2020, this regulation amends the CLP Regulation with the introduction of Annex VIII. The new annex sets out harmonised submission requirements for the notification of information to Poison Centres. Although an exemption for mixtures supplied solely for industrial use was not provided, distinctions were made between mixtures for consumer use, professional use and industrial use. Successive deadlines apply for the submission of information to Poison Centres, depending on the intended use of the mixture; mixtures, including alloys, intended for use only at industrial sites benefit from the longest deadline (1 January 2024).

13. Is lead metal now a REACH Substance of Very High Concern that will require authorisation in future? **UPDATED**

Lead metal was included on the Candidate List of Substances of Very High Concern (SVHCs) on 27 June 2018. Therefore, lead metal is now regarded as an SVHC and is eligible for inclusion in REACH Annex XIV (the 'Authorisation List').

For more information on the status of lead metal in the Authorisation process, please see the frequently asked question, "Is the use of lead metal subject to REACH Authorisation?", on the Consortium's website and the list of FAQs on the Candidate Listing of lead metal referred to therein.

14. Lead metal is already restricted according to Entry 63 of Annex XVII to REACH. Are there other REACH restrictions foreseen in light of the 9th ATP to CLP? **UPDATED**

Regulation (EU) 2017/1510 amending Annex XVII to REACH, the list of restrictions, entered into force in September 2017. The Annex XVII update adds a number of CMR 1A and 1B substances in Appendices 1 to 6 to which Annex XVII Entries 28-30 refer; due to its classification as a Category 1A reproductive toxicant, lead metal (in massive and powder forms) is included in Appendix 5 from 1 March 2018.

From that date, the placing on the market and use of lead metal as a substance, as a constituent of other substances, or, in mixtures (including alloys), for supply to the general public will be prohibited when the individual concentration in the substance or mixture is equal to or greater than the relevant concentration limit, i.e. 0.03% for lead metal powder, and 0.3% for lead metal in massive form. Suppliers must ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly, '**Restricted to professional users**'.

This restriction and the labelling obligations would not apply to the use of articles such as ammunition and architectural lead sheet, nor to the industrial or professional use of lead metal on its own or in a mixture.

Separately, restrictions on (i) the use of lead shot for shooting over wetlands, (ii) the use of lead in hunting in terrestrial areas, lead ammunition, and lead in fishing sinkers are being progressed by the European Union and the European Chemicals Agency.

In 2017, ECHA carried out a review of the restriction on lead in jewellery, which was required by 9 October 2017, focussing on the existing derogations and on whether a migration limit should be introduced to the restriction. At the time of writing, outcomes of the review are awaited.

15. My company supplies lead-containing alloys (pre-fabrication) for which we have bioelution data. Is there a derogation from the restriction on the supply to consumers based on bioavailability estimates of lead release data?

Bioelution is a tool, still under development, which may eventually be adopted as a method to estimate bioavailability when assessing human health risks from exposure to metals. If accepted by regulators, and if the data were favourable, bioelution could potentially be used in an improved approach for the self-classification of alloys.

However, the restriction on the supply to consumers of lead as a substance and in mixtures, including alloys, is based on lead content. There is no derogation from the restriction based on a supplier's self-classification of a mixture, nor on lead release test data or bioavailability estimates. From 1 March 2018, lead is listed in Appendix 5 to REACH Annex XVII and is consequently restricted by Entry 30 of Annex XVII. As such, from that date all mixtures containing 0.3% or more lead metal massive or 0.03% or more lead powder cannot be supplied to the general public.

16. How does the change in CLP classification for lead metal affect other legislation?

Transport

The harmonised classification introduced by the 9th ATP to CLP for lead metal does not effect a change in transport classification.

In general terms, the classification criteria under transport legislation are harmonised with those of the Globally Harmonised System (GHS), on which the CLP Regulation is based. However, not all hazard classes and categories found in CLP feature in the existing transport legislation. Reproductive toxicity and STOT-RE are examples of hazard classes in CLP which are not in scope of transport legislation – the latter is used to prevent, as far as possible, harm to human health or the

environment in the case of accidents during carriage, i.e. where no repeated and prolonged exposure takes place.

The latest SDS templates for lead metal powder and the 'lead metal with arsenic' grade have been amended, now indicating, where relevant, the UN Number (UN3077), Proper Shipping Name (ENVIRONMENTALLY HAZARDOUS SUBSTANCES, SOLID, N.O.S. (<substance name>) and other transport information applying to those grades. However, this change is not a consequence of the harmonised classification for lead metal introduced by the 9th ATP to CLP.

Seveso Directive

The harmonised classification introduced by the 9th ATP to CLP does not change the Seveso status of lead metal in massive or powder forms.

'Lead metal with arsenic' grade was already in scope of the Seveso Directive where the amount of arsenic present is ≥2.5%, due to the resultant environmental classification (Aquatic Chronic 2 (H411)). Similarly, lead metal powder was also already in scope due to its classification as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

Storage of hazardous materials

No additional storage arrangements are required as a consequence of the revised classification for lead metal introduced by the 9th ATP to CLP.

17. Are other changes to the classification of lead metal foreseen? **UPDATED**

Lead metal powder is currently classified by the Lead REACH Consortium as H400 (M-factor: 10) and H410 (M-factor: 1), but the high purity and general grades of lead metal massive do not currently carry environmental classification. The difference is based on the use of Transformation/Dissolution (TDp) data and the modelling of metal speciation (Unit World Model, UWM).

In March 2014 and again in September 2017, the Danish Competent Authority submitted a proposal for harmonised environmental classification, proposing classification as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M-factors of 10 for all forms of lead metal. Should the proposed harmonised environmental classification be applied, the high purity and general grades of lead metal massive would be brought into scope of Transport legislation and the Seveso Directive.

Further information on the status of the harmonised environmental classification proposal is available on the ECHA website.