Pb metal: Q&A on classification, concentration limits, thresholds and communication obligations

Lead REACH CONSORTIUM

Introduction

This document has been prepared to address common questions about the impact of Candidate Listing, the obligations of suppliers of products made with Pb metal, and the potential need for REACH Authorisation should Pb metal be included in REACH Annex XIV.

If you have a question that is not covered here, please contact ILA (reach@ila-lead.org) for more information.

The following questions concern Candidate Listing of Pb metal and consequent obligations:

1. What hazard or concern led to the Candidate Listing of Pb metal?

Lead metal was included on the Candidate List in respect of its classification as a Category 1A reproductive toxicant; the classification was assigned due to effects on both fertility and development.

The 9th ATP[1] to the CLP Regulation introduced two harmonised classification and labelling (CLH) entries for health for lead metal, which were added to Table 3.1 of Part 3 of Annex VI. One entry applies to lead metal in powder form (particle diameter <1mm) and one to lead metal massive (particle diameter ≥1mm), as presented in the following table:

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		

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, in addition to the harmonised health classification, the Lead REACH Consortium has assigned STOT RE1 (H372) to Pb metal in all forms, based on systemic availability of the lead cation.

Additionally, the Lead REACH Consortium has self-classified Pb metal powder as Aquatic Acute 1 (H400; M-factor 10) and Aquatic Chronic 1 (H410; M-factor 1). Currently, no environmental classification applies to Pb metal in massive form.

[1]Regulation (EU) 2016/1179; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1179

2. When is a SDS required for Pb metal as a substance or in a mixture?

An SDS must be provided where Pb metal is:

- supplied as a substance on its own,
- present as an impurity in another substance, causing it to be classified as hazardous (see Qu. 3), and
- present in a mixture or pre-fabricated alloy, causing it to be classified as hazardous (see Qu. 3). ((*REACH Article 31 (1)(a)*)

A supplier must also provide the recipient with an SDS *on request* where Pb metal is present in a mixture that is not classified as hazardous. *(REACH Article 31 (3)(c).)* That obligation applies because Pb has Community workplace exposure limits; no concentration threshold applies to Article 31 (3)(c), thus overriding Article 31 (3)(a-b). *(See ECHA Guidance on the compilation of safety data sheets, Version 3.1 November 2015, Page 22.)*

There is no requirement to provide SDS for articles such as engineering/machinery components fabricated from leaded alloys, lead-based batteries, architectural lead sheet, weights, ammunition.

3. What concentration limits apply when classifying substances and mixtures containing Pb metal?

Classifying for health effects

A substance or mixture will be classified for health effects if the concentration of Pb metal is present (as a constituent or impurity) at or above the relevant concentration limit[2].

In the case of Pb metal in powder form, two SCLs are assigned; they apply to developmental toxicity and repeat-exposure specific target organ toxicity (STOT RE). Therefore, for substances and mixtures containing Pb metal in powder form, the following concentration limits apply:

- Repro. 1A; H360D: ≥0.03% for effects on development – SCL *(Regulation (EU) 2016/1179)*
- Repro. 1A for effects on fertility applies ≥0.3% – GCL *(CLP Annex I, Part 3, Table 3.7.2)*
- Lact.; H362: ≥0.3% – GCL *(CLP Annex I, Part 3, Table 3.7.2)*
- STOT RE1; H372: ≥0.5% – SCL *(self-classification)*

No Specific Concentration Limits (SCL) have been assigned to Pb metal in massive form. Therefore, for substances and mixtures containing Pb metal in massive form (including pre-fabricated alloys), the following Generic Concentration Limits (GCL) apply:

- Repro. 1A; H360FD: ≥0.3% *(CLP Annex I, Part 3, Table 3.7.2)*
- Lact.; H362: ≥0.3% *(CLP Annex I, Part 3, Table 3.7.2)*
- STOT RE1; H372: ≥10% *(CLP Annex I, Part 3, Table 3.9.4)*

[2] It may be possible to refine the classification by utilising bioaccessible metal concentrations defined using a validated and standardised bioelution protocol. Such a protocol for the oral route of exposure is currently being evaluated by the EU Reference Laboratory for alternatives to animal testing (ECVAM). Companies using bioelution to refine health classifications do so at their own risk until a validated protocol is published by ECVAM and accepted for CLP assessments by Member States.

According to Section 3.9.2.6 of the ECHA *Guidance on the Application of the CLP Criteria*[3], where classification of a mixture as STOT RE1 is not triggered, if a Category 1 constituent is present in lower concentrations than the established SCL, a classification in Category 2 should be *considered*. The Pb metal STOT RE1 classification is based upon human evidence, rather than experimental animal studies, and the dose response for central nervous system effects indicates a threshold for significant target organ toxicity at or around 40-50 µg Pb /dL blood. Therefore, through expert judgment, it was not considered necessary to apply a lower concentration limit to reflect a STOT RE2 for mixtures.

Classifying for environmental effects

Currently, no environmental classification applies to Pb metal in massive form; the Lead REACH Consortium has self-classified Pb metal powder as H400-H410, with an Acute M-factor of 10 and a Chronic M-factor of 1. Environmental classification of substances and mixtures containing Pb metal is carried out according to Tables 4.1.1 (for acute effects) and 4.1.2 (for chronic effects) in CLP Annex I.

Tables 2 and 3 below summarise the classification of substances and mixtures containing Pb metal in massive and powder forms respectively.

4. When is communication in the supply chain required for Pb metal in articles?

Where an article such as a fabricated engineering component contains more than 0.1% by weight of Pb metal, the supplier must provide information to the recipient which allows for safe use of the article. As a minimum, the supplier must name Pb metal as the SVHC present. *(REACH Article 33)*

Article 33 disclosure must be proactive where the recipient is an industrial or professional user, or a distributor (including retailers) – i.e. for business-to-business supply. *(REACH Articles 33 (1) & 3 (35))*

Where the article is supplied to a consumer, the same information must be provided free of charge and in writing within 45 days of a request. *(REACH Article 33 (2))*

In the case of complex objects (i.e. objects made up of more than one article joined or assembled together), the 0.1% threshold applies to each article. *(Judgement of the European Court of Justice of 10 September 2015 in case C-106/142[4])*

5. When is Article 7(2) notification required?

A producer or importer of an article containing Pb metal must notify ECHA if both of the following conditions are met *(REACH Article 7 (2))*:

- Pb metal is present in those articles above a concentration of 0.1% (w/w), and
- Pb metal is present in those articles in quantities totalling over one tonne per producer or importer per year.

The notification must be submitted by the importer/producer no later than 6 months after the substance was included in the Candidate List. *(REACH Article 7 (7))*

However, a notification is not required when:

[3] https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5
[4] http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14

- the article producer or importer can exclude exposure of humans and the environment during the use and disposal of the article *(REACH Article 7 (3))*, or
- the substance has already been registered for that use. *(REACH Article 7 (6))*

In the case of complex objects (i.e. objects made up of more than one article joined or assembled together), the 0.1% threshold applies to each article. *(Judgement of the European Court of Justice of 10 September 2015 in case C-106/142)*

Summary of SDS obligations, classification, and label elements related to Pb metal in articles (Table 1), as a constituent or impurity in another substance or mixture in massive form (Table 2), and as a constituent or impurity in another substance or mixture in powder form (Table 3)

Table 1 SDS obligations, hazard classification, and label elements related to Pb metal in articles

Material	Lead content (w/w)	Hazard classification	Label elements	SDS mandated?
Lead-containing **ARTICLES** (e.g. engineering components fabricated from leaded alloys	Any	Not applicable	Not applicable	No – but Art. 33 applies if Pb >0.1% in the article

Tables 2 and 3 below assume there are no other constituents or impurities present which contribute to classification.

Note: as Pb concentration increases (i.e. moving down the table within a given form of Pb metal), new/amended hazard classes and categories shown in **bold purple text** in column 'Hazard classification'.

Table 2 SDS obligations, hazard classification, and label elements related to Pb metal as a constituent or impurity in substances and mixtures in massive form

Material	Lead content, *C* (w/w)	Hazard classification	Label elements		SDS mandated?
Mixtures / alloys – **MASSIVE*** [particle diameter ≥ 1 mm]	0% < C < 0.3%	None	None		On request of recipient
	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 ≥ 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

** Currently, no environmental classification applies to Pb metal in massive form (except where triggered by impurities (such as arsenic))*

Table 3 SDS obligations, hazard classification, and label elements related to Pb metal as a constituent or impurity in substances and mixtures in powder form

Material	Lead content, *C* (w/w)	Hazard classification	Label elements		SDS mandated?
Mixtures / alloys – **POWDER**; [particle diameter < 1 mm]	0% < C < 0.03%	None	None		On request of recipient
	0.03% ≤ C < 0.25%	**Repr. 1A; H360D**		Danger H360D: May damage the unborn child	Yes
	0.25% ≤ C < 0.3%	Repr. 1A; H360D **Aquatic Chronic 3; H412**		Danger H360D: May damage the unborn child H412: Harmful to aquatic life with long lasting effects	Yes
	0.3% ≤ C < 0.5%	Repr. 1A; H360FD **Lact.; H362** Aquatic Chronic 3; H412		Danger H360FD: May damage fertility. May damage the unborn child H362: May cause harm to breast-fed children H412: Harmful to aquatic life with long lasting effects	Yes
	0.5% ≤ C < 2.5%	Repr. 1A; H360FD Lact.; H362 **STOT RE 1; H372** Aquatic Chronic 3; H412		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. H412: Harmful to aquatic life with long lasting effects	Yes
	2.5% ≤ C < 25%	Repr. 1A; H360FD Lact.; H362 STOT RE 1; H372 **Aquatic Acute 1; H400** **Aquatic Chronic 2; H411**		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 H400: Very toxic to aquatic life H411: Toxic to aquatic life with long lasting effects	Yes

	C ≥ 25%	Repr. 1A; H360FD Lact.; H362 STOT RE 1; H372 Aquatic Acute 1; H400 **Aquatic Chronic 1; H410**		Danger	Yes
			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 H410: Very toxic to aquatic life with long lasting effects		

The following questions concern REACH Authorisation, should Pb metal be added to Annex XIV:

6. How would REACH Authorisation apply where Pb metal is present in another substance or in a mixture (including in pre-fabricated alloys)?

REACH Authorisation would generally be required for any use of Pb metal as a substance or in a mixture in the EU/EEA where exemption did not apply.

General exemptions would apply to:

- Pb metal as a non-isolated intermediate *(REACH Article 2 (1)(c))*
- Pb metal as an isolated on-site or transported intermediate *(REACH Article 2 (8)(b))*
- Use of Pb metal in scientific research and development i.e. any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year *(REACH Article 3 (23))*.

(Other exemptions as listed in Article 56 (4) and (5) are not expected to be relevant to Pb metal.)

If any use-specific exemptions were granted under Article 58 (2), they would be listed explicitly in the Annex XIV entry for Pb metal, should it be added to the Authorisation List.

REACH Authorisation would also not be required where Pb metal is **present in a mixture** below the cut-off values specified in CLP Article 11(3) which result in the classification of the mixture as hazardous. *(REACH Article 56 (6)(b))*

In practice, this means Authorisation would generally be required (unless another exemption applies) where Pb is present:

- ≥ 0.03% – powder form *(CLP Annex I, Section 1.1.2.2.2 (a)(ii); Annex VI, Index No. 082-013-00-1)*
- ≥ 0.3% – massive form *(CLP Annex I, Section 1.1.2.2.2 (a)(iv) with Table 3.7.2; Annex VI, Index No. 082-014-00-7)*

Note that these limit values, which define when Authorisation may be required for Pb as present in a mixture, are indeed different to the 0.1% w/w threshold triggering Article 33 communication and Article 7(2) notification duties for Pb metal as a Candidate List substance in articles (see Questions 4 and 5 respectively). Also note that, from 5 January 2021, another notification requirement will apply, which is designed to promote the reduction of the content of hazardous substances in materials and products. From 5 January 2021, suppliers of articles will also be required to submit REACH Article 33(1) information to an ECHA database for substances in articles. *(Article 9 of Directive (EU) 2018/851)*

REACH Authorisation for Pb metal would also not be required where Pb metal is **present in another substance** used, as an impurity (for well-defined substances) or other constituent (e.g. for UVCBs), if this other substance is not included in Annex XIV (see also ECHA FAQ ID [0565], Version 1.0 of 04/06/2015[5]).

[5] Available at https://echa.europa.eu/support/qas-support/qas

7. Would Authorisation apply if Pb metal was present only as an impurity?

To some extent, this topic is discussed in ECHA Q&A question [0565][6].

In late 2017, CARACAL issued a paper[7] describing a wide interpretation of the scope of REACH Authorisation for materials that contain substances on Annex XIV as part of another substance or a mixture. The opinion of CARACAL would appear to be that Authorisation would be required even if Pb metal were only present as an impurity in a mixture at or above the relevant concentration limits noted in Qu.6 (i.e. ≥ 0.03% in powder form; ≥ 0.3% in massive form). There is ongoing work, which included a critical legal review of the paper, within the sector to reopen discussions with Member States and the European Commission given the impacts and consequences of the CARACAL position. The Taskforce will be kept informed of that initiative and any key outcomes or developments.

8. Would Authorisation be required for material recovery operations?

When the resulting material is no longer waste, material recovery operations such as secondary production of non-ferrous metals are considered manufacturing under REACH. Manufacturing itself is not subject to REACH Authorisation.

According to the CARACAL paper (CA/98/2017), the Authorisation obligation would appear to apply to the use of Pb metal in a mixture recovered from waste where Pb is present at or above the relevant concentration threshold noted in Qu. 6 (i.e. ≥ 0.03% – powder form; ≥ 0.3% – massive form) – however, see also the response to Qu. 7.

[6] https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Authorisation

[7] "REACH Authorisation - Relevance of the 80/20% rule used in substance naming and identification in determining authorisation obligations under REACH for recovered substances on their own or in mixtures" (CA/98/2017)