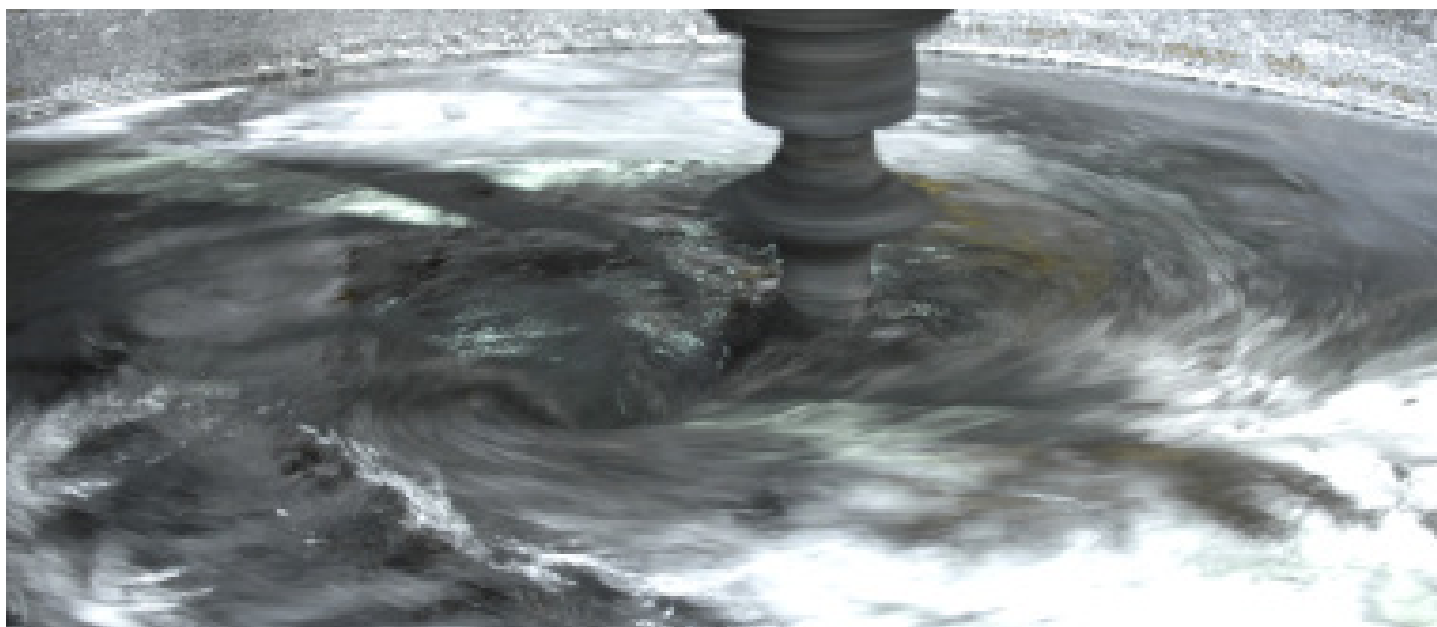


INFORMATION

Hazardous substance classification of lead-metal



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CONTENTS

Background and status

Immediate consequences of classification

Communications with suppliers, customers and consumers

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Note regarding exclusion of legal obligation:

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CONTENTS

1. Background and status	page 2
2. Immediate consequences	page 4
3. Communications with suppliers, customers and consumers	page 6
4. Contact	page 7

1. Background and status

With the decision of the REACH committee on 3/4 February 2016, and the publication of the 9. alignment regulation to the CLP Regulation, the implementation of the classification of lead-metal as toxic for reproduction category 1A is now pending. This paper offers affected companies instructions and help for dealing with inquiries from suppliers, customers or consumers.

At the end of December 2013, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) recommended, upon application by Sweden, that lead-metal be classified as toxic for reproduction, that is, as the highest category 1A. The RAC recommendation also includes a very low specific concentration limit (SCL) for lead of 0.03% (300 ppm). Any mixture or compound (such as alloys) that exceeds the limit must also be classified as toxic for reproduction on account of its lead content.

Following the RAC recommendation, further discussions with the participation of the EU Commission and the EU Member States took place as part of the Article 133 Committee (REACH regulatory committee). It was this committee that ruled in February 2016 on this classification. On the basis of the technical aspects contributed by the European metal industry, the classification was refined and now contains a generic concentration limit (GCL) for solid material (particularly alloys) of 0.3%, as well as a specific concentration limit of 0.03 for material in powder form (< 1mm). Accordingly, Appendix VI of the CLP Regulation of harmonised classifications contains two entries. In the case of solid lead, the entry for the specific concentration limit remains empty, because the generic limit of 0.3% (generic concentration limit, GCL) is applied here (Table 1).

In connection with the reclassification of lead one must note that recital 4 contains instructions about varied bioavailability and, thus, a justification for the aforementioned differentiation of concentration limits:

“With regard to the substance lead, RAC proposes in its scientific opinion of 5 December 2013 to classify it as toxic for reproduction category 1A. However, in view of the lack of certainty regarding the bioavailability of lead in the massive form, a distinction needs to be made between the massive form (particle size more than or equal to 1 mm) and the powder form (particle size of less than 1 mm). It is therefore appropriate to introduce a specific concentration limit (SCL) of $\geq 0,03\%$ for the powder form and a generic concentration limit (GCL) of $\geq 0,3\%$ for the massive form.”

As a result, the effect of the classification of lead-metal on other metals and/or lead-containing alloys may be refined once the further development and validation of the bioelution method has been completed.



Table 1: Entry in Annex VI of the CLP Regulation regarding the harmonised classification of lead

INDEX NO.	INTERNAT. CHEMICAL IDENTIFICATION	EG 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)	
082-013-00-1	lead powder [particle diameter < 1 mm]	231-100-4	7439-92-1	Repr. 1 A Lact.	H360FD H362	GHS08 Dgr	H360FD H362	Repr. 1 A; H360D: C $\geq 0,03\%$
082-014-00-7	lead massive [particle diameter ≥ 1 mm]	231-100-4	7439-92-1	Repr. 1 A Lact.	H360FD H362	GHS08 Dgr	H360FD H362	

This classification, which was published on 19.07.2016, will be implemented via an alignment regulation to the CLP Regulation (9. ATP = 9. Adaptation to Technical Progress). Following a transitional period of 21 months, the classification will become immediate legally binding for all EU Member States on 01.03.2018.

The harmonised classification at first will concern only the 'end point' considered, that is, the properties that are toxic for reproduction:

Table 2: Health-classification, labelling elements and obligation to provide safety data sheets (SDS) upon entry into force of the harmonised classification of lead

MATERIAL	LEAD CONTENT	CLASSIFICATION	LABELLING ELEMENTS	SDS REQUIRED
Articles, made of lead or lead-containing	any	Not applicable	Not applicable	no
massive, particle diameter ≥ 1 mm	$C \geq 0,3\%$	Repr. 1A H360DF 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
Powder, particle diameter < 1 mm	$C \geq 0,03\%$	Repr. 1A H360DF Lact. H362	 Danger H3H360FD: May damage fertility. May damage the unborn child H362: May cause harm to breast-fed children	yes
	$C < 0,03\%$	none	none	on request

All other properties not considered must be taken into account by manufacturers or importers in connection with the obligation of self-classification. This was addressed as part of the necessary update of the REACH dossier by the International Lead Association (ILA). An additional self-classification STOT RE1, H372 (Causes damage to organs through prolonged or repeated exposure) was therefore assigned. However, due to differences in relative bioavailability, separate concentration limits apply to the different forms:

- lead metal powder: specific concentration limit of $\geq 0.5\%$
- lead metal massive: generic concentration limit of $\geq 10\%$.

After the decision regarding classification, one must also expect that Denmark or Sweden will include it in the Registry of Intention (RoI) in order to propose the inclusion of lead in the REACH candidate list of substances (SVHC list). This would be the first step for a possible authorization requirement for uses of this metal.

2. Immediate consequences

A number of obligations will enter into effect immediately upon classification. Please see below for some important instructions:

Scope

- The classification affects only pure lead as a substance and/or mixture or alloys marketed with the aforementioned lead content. The existing harmonised classification of lead compounds, and individual entries regarding lead-containing compounds, will of course remain in place.

Safety Data Sheet and Labelling

- The classification requires that a safety data sheet (SDS) is created and delivered without request to all customers for solid lead and all mixtures (including alloys) containing lead with more than 0.3% lead by weight and/or 0.03% for lead-containing material in powder form. The safety data sheet must specify what the required protective measures are for activities involving substances toxic to reproduction. Manufacturers of block material or casting alloys, such as bars, slugs or ingots, with a lead content over 0.3% therefore have to prepare and deliver to their customers, without request, an SDS. Manufacturers of metal powder are obligated in the same manner where lead content of 0.03% or higher is concerned (Table 2). However, due to the existing European occupational exposure limit values for lead, and by way of an explanation of the classification, preparation of a safety data sheet is also recommended for solid materials with a lead content of 0.03% and higher. In all cases safety data sheets must be delivered upon request of the recipient.
- Solid metal and alloys do not need to be labelled under the CLP Regulation (Annex I, Section 1.3.4). Solid lead and all lead-containing alloys, such as ingots, slugs or slabs, therefore, do not have to be labelled using the CLP pictograms. The obligation to prepare SDS when marketing these materials remains in effect.
- Materials that companies use internally are subject to the Technical Rule for Hazardous Substances TRGS 201 in Germany. This Technical Rule requires minimum labelling and, if necessary, appropriate instructions for use.
- Articles pursuant to REACH are not subject to classification and labelling requirements. All semi-finished articles (such as sections, sheet metal, pipes or wires) constitute articles and are therefore not affected. Nor is it necessary to prepare and submit SDS. For reasons of product responsibility, however, an information paper for articles should be prepared that may well resemble the layout of a safety data sheet, but should not be referred to as such (cf. instruction paper of WVMetalle in this context).

Waste

- Waste does not fall into the jurisdiction of the CLP Regulation either. Therefore, the same exceptions apply as for articles. The provisions of the EU Waste Catalogue and of Annex III of the EU Waste Directive apply to waste, both of which follow the hazardous substances law and the classification criteria under the CLP Regulation.
- There is a general exemption for pure metal alloys in solid form in the list of wastes, so long as these are not contaminated by dangerous substances. It is generally understood that „contamination by dangerous substances“ occurs only where the surface of alloy scrap is contaminated, for instance, by oils or emulsions. As a result:
 - Alloy components (added deliberately) classified under chemicals laws never turn scrap into hazardous waste. This applies also to alloys of two or more substances classified under hazardous substances laws.
 - By way of logic, this must also apply then to minor traces of metals classified as hazardous that form a contamination in an alloy or pure metal. This scrap does not need to be classified either.

- Accordingly, this also applies to metals in pure form classified as hazardous (such as lead scrap, unalloyed).

For other „non-solid“ waste, such as slags or filter dusts, however, the hazard criteria of the Waste Directive (HP criteria) must be applied. Substances toxic for reproduction under category 1A and 1B with a content of 0.3% or higher must be classified under waste regulations. For reasons of product responsibility (as indicated in the case of articles), however, an information paper for waste should be prepared that may well resemble the layout of a safety data sheet, but should not be referred to as such (cf. instruction paper of WVMetalle in this context).

Occupational Health and Safety

- Companies may have to adapt their risk/hazard assessment in accordance with occupational health and safety laws. In particular, all obligations according to the TRGS 505 „Lead“ still remains in effect.
- Work with lead is to be organised taking into account the maternity protection directive for expectant mothers as well as the adolescence occupational safety and health act for young worker.

Placing on the Market

- Under Annex XVII of the REACH regulation (restricted production, marketing and use of specific hazardous substances, mixtures and products), category 1A or 1B reprotoxic substances or mixtures exceeding the SCL must not be marketed or used if they are intended for sale to the general public. Furthermore, prior to marketing them, the supplier must ensure that the packaging of such substances and mixtures is labelled as „Restricted to professional users “ in a well-visible, legible and indelible manner. Concerning lead and lead-containing mixtures this restriction only become effective once it is included in a specific annex of the CLP regulation.
- Manufacturers and importers that market hazardous substances or mixtures classified as hazardous (even if they are not subject to registration) must file reports with the European Classification and Labelling Inventory. Since lead is now classified as hazardous, a report must be made with the Inventory if it is used as a component in alloys and if it exceeds the aforementioned concentration limits in the alloys. If you have already registered lead under the REACH regulation, you will not have to file a separate report. Reporting is free of charge and must be carried out or updated by the time that the harmonised classification enters into effect (that is from 1st March 2018 onwards). A report may be filed electronically via REACH-IT, which requires having an account. The easiest way is to file a report using the online tool, where you consent to the harmonised classification by clicking the „I agree“ button. Specific instructions on notifying substances for inclusion in the Classification and Labelling Inventory can be found in the practical guide of ECHA: http://echa.europa.eu/documents/10162/13643/pg_7_clp_notif_en.pdf
- At the national level, there is an additional reporting obligation regarding hazardous mixtures (including also alloys) under the provisions of Art. 45 of the CLP Regulation (cf. information paper of WVMetalle). This does not apply to lead as a substance as such or to lead-containing articles. This obligation is to ensure that information is reported to the poison information centres – based on Section 16e Chemicals Act, the provisions of which are expected to remain in effect until the reporting obligation has been harmonised across the EU. The reporting obligation comprises all hazardous substances, regardless of whether they are intended for private end users or for industrial or commercial use. There is no de minimis limit for small quantities. A report can be filed with the German Federal Institute for Risk Assessment (BfR) via a template, but it is easier to submit the SDS electronically to the information system for safety data sheets (ISi): <http://www.dguv.de/ifa/GESTIS/ISi-Informationssystem-f%C3%BCr-Sicherheitsdatenbl%C3%A4tter/index-2.jsp>

Other legislative Consequences

- The harmonised classification does not change the Seveso status of lead-metal or lead-powder. Lead-metal is not within the scope of the Seveso Directive 2012/18/EU. Lead-powder is already in scope due to its classification as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).
- The harmonised classification for lead-metal does not effect a change in transport classification. It is arranged 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.
- Further legal consequences of classifications as such and in particular the lead metal classification (cf. page 62 ff.) are also explained in a current expert opinion by the German Federal Ministry for Labour and Social Affairs (BMAS):
http://www.gkv.de/assets/uploads/1512_BMAS_Gutachten.pdf
<http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Einstufung-und-Kennzeichnung/Rechtsfolgen.html>
(Documents are only available in German language)

3. Communications with suppliers, customers and consumers

As a result of the classification of lead-metal, there will be inquiries, particularly from customers. Apart from the immediate obligations, it is important to respond consistently and give identical answers. See below for instructions that you can use as a guideline for your own responses.

Risks did not change

- The classification generally reflects the intrinsic properties of a substance and is not a statement about the actual risk potential in actual situations, that is, it is not a risk assessment.
- The potentially negative properties of lead – including effects toxic for reproduction – as such are not new. All previous proper and necessary protective measures taken in connection with handling lead-containing materials will therefore remain in effect unchanged.

All uses are still valid

- The technological advantages of using lead as an additive in alloys are not affected by the classification.
- Application requirements, such as the evaluation criteria for metal materials in contact with drinking water (German Federal Environment Agency's (UBA) „Hygiene List“), including the specifications contained therein regarding the by-element lead, will continue to remain in effect (https://www.umweltbundesamt.de/sites/default/files/medien/376/dokumente/bewertungsgrundlage_fuer_metallene_werkstoffe_im_kontakt_mit_trinkwasser.pdf; this document is only available in German).

Occupational measures in Germany already take into account lead specificities

- In Germany lead in bioavailable form has been classified as toxic for reproduction for some time (see TRGS 905), and the appropriate protective measures will continue to remain in effect. TRGS 505 „Lead“, in particular, contains special protective measures in connection with the handling of lead, inorganic lead compounds and lead-containing mixtures – it remains in effect. Preparations are currently under way to adapt TRGS 505 to the classification, including any modifications to evaluation criteria regarding occupational safety.

There are no immediate consequences under REACH at the moment

- The classification meets the legal prerequisite for inclusion in the SVHC list pursuant to the REACH regulation, subject to a motion brought by a Member State. This is expected shortly (see above). But an obligation to communicate with customers will be in effect only once inclusion in the SVHC list has been completed officially.
- At first, the modified classification does not place any direct restriction on the further use of lead, nor does it create an authorization requirement under the REACH regulation. In fact, as part of the activities of the Cross Industry Initiative (CII), the focus is primarily on occupational safety provisions. The conditions in this context are good especially for lead, given existing European occupational exposure limit values.

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