

Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: Lead (lead powder and lead massive)

EC Number: 231-100-4

CAS Number: 7439-92-1

Submitted by: Swedish Chemicals Agency

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EC Number: 231-100-4

CAS number: 7439-92-1

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class reproductive toxicity category 1A¹.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Lead is covered by index numbers 082-013-00-1 (lead powder) and 082-014-00-7 (lead massive) of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 1A (hazard statement H360FD: "May damage fertility. May damage the unborn child"¹) and effects on or via lactation (hazard statement H362: "May cause harm to breast-fed children").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Reproductive toxicity category 1A in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes

¹ Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

PART I

Justification

1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	231-100-4
EC name:	Lead
CAS number (in the EC inventory):	7439-92-1
CAS number: Deleted CAS numbers:	
CAS name:	
IUPAC name:	
Index number in Annex VI of the CLP Regulation	082-013-00-1 (lead powder) 082-014-00-7 (lead massive)
Molecular formula:	Pb
Molecular weight range:	207.2 g/mol
Synonyms:	

Structural formula: Pb

1.2 Composition of the substance

Name: lead

Description: inorganic

Substance type: mono-constituent

1.3 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

2. Harmonised classification and labelling

Lead is covered by Index numbers 082-013-00-1 (lead powder) and 082-014-00-7 (lead massive) in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as listed in Commission Regulation (EU) 2016/1179 of 19 July 2016)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				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]	23-10-0-4	74-39-0-92-1	Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362		Repr.1 A; H360D : C ≥ 0.03 %	
082-014-00-7	lead massive: [particle diameter ≥ 1 mm]	23-10-0-4	74-39-0-92-1	Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362			

H360FD: May damage fertility. May damage the unborn child.
H362: May cause harm to breast-fed children.

3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

4. Human health hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Lead is covered by index numbers 082-013-00-1 (lead powder, particle diameter <1 mm) and 082-014-00-7 (lead massive, particle diameter \geq 1 mm) of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 1A (hazard statement H360FD: "May damage fertility. May damage the unborn child" and hazard statement H362: "May cause harm to breast-fed children").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Reproductive toxicity category 1A in accordance with Article 57 (c) of REACH.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3: Registration status

From the ECHA dissemination site ²	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications ³
Number of aggregated notifications	58
Total number of notifiers	1587

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ²	1 000 000 - 10 000 000 t/pa
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9. Information on uses of the substance

In the EU, metallic lead is mainly used in lead-acid batteries and in lead sheets used in the building sector. Lead is also used as shots and bullets for ammunition and for alloying steel, in soldering alloys, cable sheathing and for the production of oxides, pigments, stabilisers and other lead compounds (LDAI, 2008). According to data compiled by the International Lead and Zinc study group, the total European usage of lead metal reached 1,517,000 tonnes in 2015 (information provided by Lead REACH Consortium, based on the report Main First Uses of Lead and Zinc in Europe 2017, by the International Lead and Zinc Study Group).

² <https://echa.europa.eu/substance-information/-/substanceinfo/100.028.273>
(accessed 2018-01-08)

³ C&L Inventory database, <http://echa.europa.eu/web/quest/information-on-chemicals/cl-inventory-database>
(accessed 2018-01-08)

According to the REACH registration metallic lead is used as indicated in table 6 below.

Table 6: Uses⁴

	Use(s)	Registered use	Use in the scope of Authorisation
Uses as intermediate		No (source: registration dossier at ECHA's dissemination site)	No
Formulation or repacking	Lead is used in: <ul style="list-style-type: none"> - formulation of mixtures - formulation in materials 	Yes	Yes
Uses at industrial sites	Lead is used at industrial sites in production of: <ul style="list-style-type: none"> - batteries - lead sheets - leaded steels - hot-dip galvanized steel - lead powder - a range of lead articles (e.g. cast, rolled and extruded products, ammunition and lead shot) Use of: <ul style="list-style-type: none"> - solder alloy, solder paste, flux cored solder wire, solder wire, solder bar - lead metal in lead oxide production and use of lead oxide in stabiliser production - molten lead as heat transfer fluid in closed process 	Yes	Yes
Uses by professional workers	Lead is used by professional workers as: <ul style="list-style-type: none"> - lead solder - lead ammunition (non-military) - articles with expected dermal contact - installation and maintenance of lead sheet - assembly of lead acid batteries - leaded steels - inert anodes 	Yes	Yes
Consumer uses*	Consumer uses of lead include use of: <ul style="list-style-type: none"> - articles with expected dermal exposure - external and internal lead sheet - articles with no expected exposure - sealed batteries - solder - lead ammunition - lead during the process of reloading spent ammunition rounds 	Yes	Yes
Article service life	Lead articles service life includes: <ul style="list-style-type: none"> - batteries, lead sheets, hot-dip galvanized steel, lead solder, lead ammunition (non-military), articles with or without expected dermal contact, inert anodes, lead powder, and a range of lead articles 	Yes	Yes

⁴ From ECHA's dissemination site: <https://echa.europa.eu/registration-dossier/-/registered-dossier/16063> and <https://echa.europa.eu/substance-information/-/substanceinfo/100.028.273> (both accessed 2017-12-04).

*Since lead is classified as Repr. 1A it is covered by entry 30 in Annex XVII of REACH (as of 2018-03-01). This means it is restricted as such and in mixtures placed on the market for sale to the general public.

The EU uses of lead are shown in Table 7 below. As can be seen in the table, the majority of lead is used in the manufacture of lead-acid batteries (84% of the total volume).

Table 7: EU uses of lead in 2015 (information provided by Lead REACH Consortium based on the report Main First Uses of Lead and Zinc in Europe, by the International Lead and Zinc Study Group)

Area of application	Volume tonnes*
Batteries	1,274 000 (84%)
Rolled and extruded products	91 000 (6%)
Shot and ammunition	61 000 (4%)
Lead compounds	61 000 (4%)
Miscellaneous (including alloys and solders)	15 000 (1%)
Cable sheathing	15 000 (1%)

*The total European usage of lead metal reached 1,517,000 tonnes in 2015, according to data compiled by the International Lead and Zinc Study Group.

Import/export/intra EU trade of lead in the EU is presented in Table 8 below.

Table 8: Import, export and intra-EU trade of lead raw materials. Average values 2005-2010 (Eurostat⁵)

	Lead ores and concentrates tonnes per year	Lead waste and scrap tonnes per year
Imports to EU27	245,000	264,000
Exports from EU27	124,000	399,000
Intra EU trade	298,000	157,000

Lead can be considered to have wide dispersive use because:

- the reported uses include professional use, consumer use and articles service life.
- lead is registered for PROC 5 (mixing and blending in batch processes) and PROC 23 (open processing and transfer with minerals/metals at elevated temperature), indicating a high potential for exposure to humans⁶.

10. Information on structure of the supply chain

Metallic lead is used in many different areas of application and in the production of a range of substances and articles. The main lead consuming industry in the EU includes batteries, where automotive SLI lead-acid batteries are the largest use of lead, 53%, and industrial batteries account for 31% (bilateral correspondence, Lead REACH Consortium, December 2017). In 2001, the ILA reported that there were around 500 manufacturers of lead-acid batteries (worldwide), of which 27% of the market was in Europe (ILA, 2001a).

⁵ Eurostat. Available at: <http://ec.europa.eu/eurostat>

⁶ ECHA guide to the manual screening of substances for CoRAP and for the SVHC Roadmap to 2020, page 15, 27 Jan 2017.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

So far, 31 lead-containing compounds are already included in the Candidate list (Table 9). These compounds have similar toxicological properties and are all included in the Candidate list because of reprotoxic properties. Five of the listed lead compounds are also included because of carcinogenic properties.

Three lead compounds are included in REACH Annex XIV (lead chromate, lead sulfochromate yellow and lead chromate molybdate sulphate red, entry 10, 11 and 12, respectively). Four other lead compounds (orange lead, lead monoxide, pentalead tetraoxide sulphate, tetralead trioxide sulphate) were recommended by ECHA to be included in Annex XIV to REACH in the 7th Annex XIV recommendation, 10 November 2016.

Table 9: Lead compounds in the REACH candidate list

Name	EC no.	CAS no.	Reason for inclusion	Date of inclusion
Lead di(acetate)	206-104-4	301-04-2	Toxic for reproduction (Article 57c)	16/12/2013
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	Toxic for reproduction (Article 57c)	19/12/2012
Acetic acid, lead salt, basic	257-175-3	51404-69-4	Toxic for reproduction (Article 57c)	19/12/2012
Dioxobis(stearato)trilead	235-702-8	12578-12-0	Toxic for reproduction (Article 57c)	19/12/2012
Fatty acids, C16-18, lead salts	292-966-7	91031-62-8	Toxic for reproduction (Article 57c)	19/12/2012
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	Toxic for reproduction (Article 57c)	19/12/2012
Lead cyanamidate	244-073-9	20837-86-9	Toxic for reproduction (Article 57c)	19/12/2012
Lead dinitrate	233-245-9	10099-74-8	Toxic for reproduction (Article 57c)	19/12/2012
Lead monoxide (lead oxide)	215-267-0	1317-36-8	Toxic for reproduction (Article 57c)	19/12/2012
Lead oxide sulfate	234-853-7	12036-76-9	Toxic for reproduction (Article 57c)	19/12/2012
Lead titanium trioxide	235-038-9	12060-00-3	Toxic for reproduction (Article 57c)	19/12/2012
Lead titanium zirconium oxide	235-727-4	12626-81-2	Toxic for reproduction (Article 57c)	19/12/2012
Orange lead (lead tetroxide)	215-235-6	1314-41-6	Toxic for reproduction (Article 57c)	19/12/2012
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	Toxic for reproduction (Article 57c)	19/12/2012
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	Toxic for reproduction (Article 57c)	19/12/2012
Silicic acid (H ₂ SiO ₅), barium salt (1:1), lead-doped	272-271-5	68784-75-8	Toxic for reproduction (Article 57c)	19/12/2012
Silicic acid, lead salt	234-363-3	11120-22-2	Toxic for reproduction (Article 57c)	19/12/2012
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	Toxic for reproduction (Article 57c)	19/12/2012
Tetraethyllead	201-075-4	78-00-2	Toxic for reproduction (Article 57c)	19/12/2012

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Tetralead trioxide sulphate	235-380-9	12202-17-4	Toxic for reproduction (Article 57c)	19/12/2012
Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6	Toxic for reproduction (Article 57c)	19/12/2012
Trilead dioxide phosphonate	235-252-2	12141-20-7	Toxic for reproduction (Article 57c)	19/12/2012
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	Toxic for reproduction (Article 57c)	18/06/2012
Lead diazide, Lead azide	236-542-1	13424-46-9	Toxic for reproduction (Article 57c)	19/12/2011
Lead dipicrate	229-335-2	6477-64-1	Toxic for reproduction (Article 57c)	19/12/2011
Lead styphnate	239-290-0	15245-44-0	Toxic for reproduction (Article 57c)	19/12/2011
Trilead diarsenate	222-979-5	3687-31-8	Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)	19/12/2011
Lead chromate	231-846-0	7758-97-6	Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)	13/01/2010
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)	13/01/2010
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)	13/01/2010
Lead hydrogen arsenate	232-064-2	7784-40-9	Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)	28/10/2008

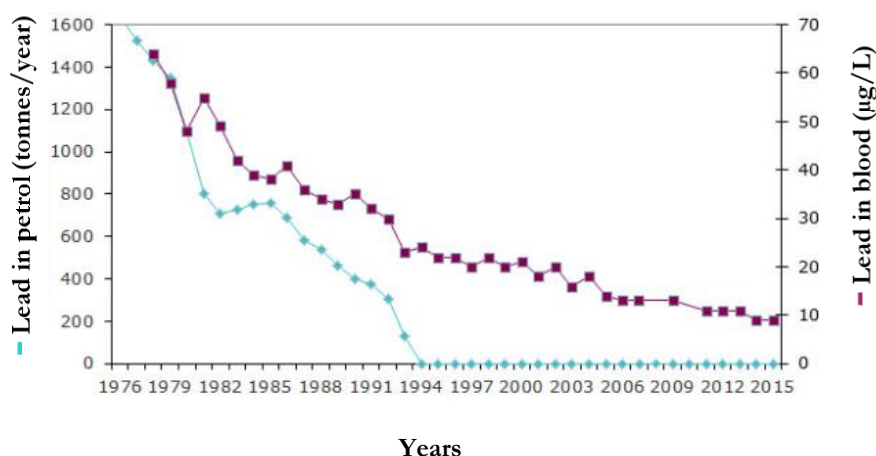
11.2 European biomonitoring data

Lead in blood is the most suitable indicator of human exposure to lead and its compounds, reflecting recent exposure. In general, a decrease in blood lead levels has been observed around the world in recent decades, primarily because of the elimination of lead in petrol. However, humans continue to be exposed to lead due to the widespread distribution of lead in the environment.

In a recent risk assessment conducted by EFSA the lowest benchmark dose derived for neurodevelopmental effects was 12 $\mu\text{g Pb/L}$, considered to result in an IQ loss of 1 point in a child (EFSA, 2010). The current blood lead levels in Western Europe are 15-20 $\mu\text{g Pb/L}$ and levels of 30-40 $\mu\text{g Pb/L}$ have been measured in Central and Eastern Europe (EFSA, 2010).

Lead in blood has been analysed in children from the South of Sweden (3-12 years old) since 1978⁷. In figure 1 below, lead in blood (median $\mu\text{g/L}$) in relation to lead in petrol (tonnes/year) is shown.

Figure 1. Lead in blood in Swedish children (1978-2015), in relation to lead in petrol. Source: The Swedish Environmental Protection Agency, Health related Environmental Monitoring Programme.



As observed in children, a recent population study of Swedish adults (1999-2014) shows a clear decrease in lead blood levels during the period following the ban on lead in petrol. However, after year 2009 no further reduction in lead blood concentrations has been observed. The levels reported for adults in 2014 are above concentrations considered safe (Wennberg et al. 2017). The data clearly demonstrates the positive effect of banning lead in petrol. On the other hand, data also shows that other sources of lead contribute to exposure, and that lead levels in blood are still high in the general population.

11.3 Alternatives

Properties of metallic lead include a low melting temperature, high ductility, slow corrosion, and a high density. These properties have made lead useful in many applications. Metallic lead has very low strength, which can be increased with small alloying additions. The high density of lead has made it useful for shielding against sound,

⁷ The Swedish Environmental Protection Agency, Health related Environmental Monitoring Programme, data provided by Lund University. Data on lead blood levels available at <http://ki.se/imm/tidsserier-och-data> (accessed 2017-12-04)

vibrations and radiation. However, other metals have similar density as lead (molybdenum, silver, and palladium) or are denser (gold, platinum, tungsten, tantalum, mercury) (ILA, 2001b).

There are a few alternatives to lead reported in the Sin List⁸, these include:

- Cables without lead, PVC and phthalates. Lead can be used as a stabiliser in PVC and by substituting the PVC with other plastics, lead and phthalates are avoided.
- Substitution on lead in fishing nets with other metals such as zinc and iron.
- Substitution of lead in PVC plastics with hydrotalcite.
- Substitution of lead in roof flashing with aluminium and trimethoxyoctylsilane.
- Alternative alloys for unleaded soldering of electronics, replacement of lead with high tin-lead free solders.

In an ongoing restriction proposal on lead stabilisers in PVC, calcium-based stabiliser systems have been suggested as substitutes⁹.

Alternatives to lead metal are also mentioned in a report from ILA (ILA, 2001c, available at: <https://www.ila-lead.org/UserFiles/File/factbook/chapter3.pdf>), some examples include:

- Aluminium, lead-clad steel and rubber backed metal, galvanised (zinc coated) steel sheet, zinc and copper as substitutes for lead in lead sheet.
- Aluminium sheaths or foils as alternatives for lead used in cable sheathing.
- Copper, steel, cadmium, concrete and barium to replace lead in radiation shielding.
- Shots of steel, bismuth and tin instead of lead.
- Zinc, bismuth-tin, other tin-based alloys and plastic coated iron, iron and stainless steel in weights instead of lead.

Disadvantages of some of the lead alternatives discussed in the report include increased manufacturing costs, higher energy consumption, increased maintenance, shorter lifetimes and worse performance of the alternative (ILA, 2001c).

Lead-acid storage batteries:

The main use of lead is as starter batteries in motor vehicles, but also as traction batteries for electric vehicles and as emergency backup batteries for computer and telecommunications systems (ILA, 2001c). At present, alternatives for some applications are under development, while for other uses alternatives are not yet available.

11.4 Existing EU legislation

Lead is harmonised classified as Repr. 1A and Lact (regulation EU 1272/2008, Annex VI, table 3.1).

REACH regulation, entries 16, 17 and 63 in Annex XVII, includes restrictions of lead and its compounds, which will decrease the risk for consumers. Furthermore, metallic lead is included in REACH Annex XVII entry 30 (as of 2018-03-01), which means it is restricted as such and in mixtures placed on the market for sale to the general public. However, lead can still be present in certain articles intended for consumer use, with potential for exposure for the general population. Given the wide range of potential uses of lead and its compounds, it cannot be ruled out that some consumer exposure may still occur.

⁸ <http://sinlist.chemsec.org/> (accessed 2017-08-22).

⁹ <https://echa.europa.eu/documents/10162/e70aee23-157b-b2a4-2cae-c42a1278072c> (accessed 2017-08-25).

Workers legislation:

According to Directive 98/24/EC (risks related to chemical agents at work), the current binding occupational limit value for inorganic lead and its compounds is 0.15 mg/m³ (8 hours TWA) and the binding biological limit value is 70 µg lead/100 mL blood. Given that health effects have been linked to significantly lower blood lead levels, the current binding biological limit value cannot be considered as sufficiently protective for workers.

According to Directive 92/85/EEC, pregnant workers and workers who have recently given birth or are breastfeeding may under no circumstances be obliged to perform duties for which there is a risk of exposure, which would jeopardise safety of health, to lead and lead derivatives. In the directive, lead and lead derivatives are the only chemical agents mentioned specifically as hazardous to this group of workers.

Batteries:

The Batteries Directive 2006/66/EC regulates the manufacture and disposal of batteries in the EU. Under the directive, there are existing requirements in terms of labelling, collection and recovering targets for lead containing batteries and accumulators. There is currently no restriction on lead in batteries, however, batteries containing more the 0.004% lead need to be labelled with the chemical symbol Pb. The recycling processes must achieve a minimum efficiency of 65% for lead-acid batteries.

Some other EU regulations related to lead include (the list is non-exhaustive):

- Regulation (EC) 1223/2009 on cosmetics
- Directive 98/70/EC on fuel quality
- RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Directive 2000/53/EC on End-of-life vehicle (ELV)
- Directive 2009/48/EC on toy safety
- Directive 94/62/EC on packaging and packaging waste
- Directive 86/278/EC on sewage sludge in agriculture
- Directive 84/500/EEC on ceramics articles intended to come into contacts with foodstuffs
- Crystal Directive 69/493/EEG

At present, a restriction proposal on lead compounds-shot is under consideration¹⁰. The proposal is to restrict the use of lead and its compounds in shot (containing lead in concentrations greater than 1% by weight) for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland, including shooting ranges or shooting grounds in wetlands. In addition, a restriction proposal on the use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds is under consideration¹¹.

11.5 Previous assessments by other authorities

Risk via food intake – (European Food Safety Authority, EFSA, 2010)

In 2010, the EFSA Panel on Contaminants in the Food Chain (CONTAM) conducted a risk assessment on lead in food (updated in 2013). The CONTAM Panel concluded that no safe levels of exposure could be established for children, so instead benchmark dose levels for

¹⁰ <https://echa.europa.eu/restrictions-under-consideration> (accessed 2018-01-18).

¹¹ <https://echa.europa.eu/restrictions-under-consideration> (accessed 2018-01-18).

critical effects were derived. The lowest benchmark dose derived for neurodevelopmental effects (BMDL01) was 12 µg Pb/L blood, corresponding to a daily exposure of 0.5 µg Pb/kg body weight (bw), which is considered to result in an IQ loss of 1 point in a child (EFSA, 2010). According to EFSA's calculation, the estimated exposure in children up to age seven exceeded the BMDL01 intake level of 0.50 µg/kg bw per day for neurodevelopmental effects. Therefore, EFSA concluded that the possibility of effects in some children could not be excluded. Furthermore, the CONTAM Panel concluded that it was not possible to exclude a risk to the developing fetus through exposure of some pregnant female consumers.

The CONTAM Panel also determined the BMDL01 for cardiovascular effects, 36 µg Pb/L blood, and for kidney effects, 15 µg Pb/L blood (corresponding to a daily intake of 1.5 µg/kg bw per day and 0.63 µg/kg bw per day, respectively).

Cancer – (International Agency for Research on Cancer, IARC, 2006)

The International Agency for Research on Cancer (IARC) has classified inorganic lead compounds as probably carcinogenic to humans (Group 2A) and organic lead compounds as not classifiable as to its carcinogenicity to humans (Group 3) (IARC 2006).

Work environment – (Scientific committee on exposure limits, SCOEL, 2002)

The Scientific committee on exposure limits, SCOEL, concluded in 2002 that based on current data no definite NOAEL (no observed adverse effect level) can be deduced, which calls for a minimisation of exposure. A biological limit value (BLV) of 30 µg Pb /100 mL blood was recommended. The SCOEL emphasised that it should be kept in mind that the recommended BLV is not seen as being entirely protective of the offspring of working women and that no threshold for potential central nervous system effects in new-borns and infants has been identified. The exposure of fertile women to lead should therefore be minimised. In addition, an OEL for airborne exposure of 100 µg/m³ was recommended.

In the EU, the current binding occupational limit value for inorganic lead and its compounds is 0.15 mg/m³ (8 hours TWA) and the binding biological limit value is 70 µg lead/100 mL blood (Council Directive 98/24/EC).

REFERENCES

References for Part I

- EU (2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
- EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
- EU (2016). Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No

1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

References for Part II

- EFSA (2010/2013): Scientific Opinion on Lead in Food. EFSA Panel on Contaminants in the Food Chain (CONTAM), European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2010 8(4):1570. Last updated 22 March 2013. This version replaces the previous one.
- EU (1969). Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass.
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