

## **Annex XV dossier**

# **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name:** Fatty acids, C16-18, lead salts

**EC Number:** 292-966-7

**CAS Number:** 91031-62-8

**Submitted by:** European Chemicals Agency at the request of the European Commission



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## **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name: Fatty acids, C16-18, lead salts**

**EC Number: 292-966-7**

**CAS Number: 91031-62-8**

The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1 A<sup>1</sup>.

### **Summary of how the substance meets the criteria set out in Article 57 (c) of REACH (Repr. 1A).**

Fatty acids, C16-18, lead salts is covered by Index number 082-001-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1A (H360D: "May damage the unborn child"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 1, R61 ("May cause harm to the unborn child").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

**Registration dossiers submitted for the substance? Yes**

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<sup>1</sup> Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

## PART I

### JUSTIFICATION

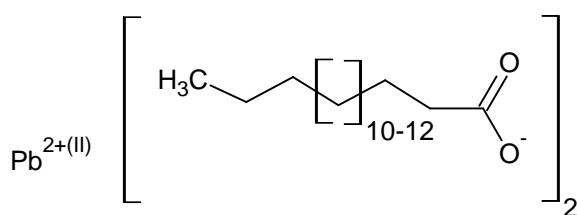
#### 1 Identity of the substance and physical and chemical properties

##### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

<b>EC number:</b>	292-966-7
<b>EC name:</b>	Fatty acids, C16-18, lead salts
<b>CAS number (in the EC inventory):</b>	91031-62-8
<b>CAS number:</b> <b>Deleted CAS numbers:</b>	91031-62-8 ---
<b>CAS name:</b>	Fatty acids, C16-18, lead salts
<b>IUPAC name:</b>	C16-18-(even numbered)-fatty acids, lead salts
<b>Index number in Annex VI of the CLP Regulation</b>	082-001-00-6
<b>Molecular formula:</b>	---
<b>Molecular weight:</b>	---
<b>Synonyms:</b>	---

**Structural formula:**



## 1.2 Composition of the substance

**Name:** Fatty acids, C16-18, lead salts

**Description:** UVCB substance

**Degree of purity:** 100 %

**Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
lead dipalmitate 239-870-3		22 - 65 %	According to the information available in the registration dossiers
lead distearate 214-005-2		35 - < 80 %	According to the information available in the registration dossiers
Fatty acids, C16-18 266-928-5		0 - 3 %	According to the information available in the registration dossiers
water 231-791-2		0 - 2 %	According to the information available in the registration dossiers
Fatty acids, < C16, lead salts ---		0 - 6 %	According to the information available in the registration dossiers
Fatty acids, > C18, lead salts ---		0 - 5 %	According to the information available in the registration dossiers

## 2 Harmonised classification and labelling

Fatty acids, C16-18, lead salts is covered by Index number 082-001-00-6 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

**Table 3: Classification according to part 3 of Annex VI, Table 3.1 ((list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008**

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)		
082-001-00-6	Lead compounds with the exception of those specified elsewhere in this Annex	-	-	Repr. 1A Acute Tox. 4* Acute Tox. 4* STOT RE 2* Aquatic Acute 1 Aquatic Chronic 1	H360Df H332 H302 H373** H400 H410	GHS08 GHS07 GHS09 Dgr	H360Df H332 H302 H373** H410		STOT RE 2; H373: C ≥ 0,5 %	A1

**Table 4: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008**

<b>Index No</b>	<b>International Chemical Identification</b>	<b>EC No</b>	<b>CAS No</b>	<b>Classification</b>	<b>Labelling</b>	<b>Concentration Limits</b>	<b>Notes</b>
082-001-00-6	Lead compounds with the exception of those specified elsewhere in this Annex	-	-	Repr. Cat. 1; R61 Repr. Cat. 3; R62 Xn; R20/22 R33 N; R50-53	T; N R: 61-20/22-33-62-50/53 S: 53-45-60-61	Xn; R20/22: C ≥ 1 % R33: C ≥ 0,5 %	AE 1



### **3 Environmental fate properties**

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

### **4 Human health hazard assessment**

*See section 2 on harmonised classification and labelling.*

### **5 Environmental hazard assessment**

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

## **6 Conclusions on the SVHC Properties**

### **6.1 CMR assessment**

Fatty acids, C16-18, lead salts is covered by Index number 082-001-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1A (H360D: "May damage the unborn child"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 1, R61 ("May cause harm to the unborn child").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

## **PART II**

### **INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS**

The available use and exposure information is provided in the registration dossiers (authorities with access rights only) or on ECHA's dissemination website<sup>2</sup>:

<http://echa.europa.eu/information-on-chemicals>

ECHA has not carried out further analysis of this information.

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<sup>2</sup> Information published by ECHA on the substance can be searched at this site (field "Search for Chemicals" at upper right) by EC number, CAS number or substance name.