Lead REACH CONSORTIUM

Grade name: Fatty acids, C16-C18, lead salts
Substance: Fatty acids, C16-C18, lead salts
EC Number: 292-966-7
CAS Number: 91031-62-8
Substance Type: UVCB
Degree of purity: 100% (w/w)
Description: Fatty acids C16-C18 consists primarily of variable amounts of lead dipalmitate and lead distearate as well as additional fatty acids and lead salts. It is primarily used as a stabiliser in plastics production.

Composition:

Constituents	Typical concentration	Concentration range	Remarks
Lead dipalmitate EC no.: 239-870-3	40 % (w/w)	>= 22 — <= 65% (w/w)	
Lead distearate EC no.: 214-005-2	52 % (w/w)	>= 35 — <= 80 % (w/w)	
Fatty Acids, <C16, lead salts EC no.: n/a	3 % (w/w)	>= 0 — < 6 % (w/w)	
Fatty acids, >C18, lead salts EC no.: n/a	2.5 % (w/w)	>= 0 — < 5 % (w/w)	
Fatty acids, C16-18 EC no.: 266-928-5	1.5 % (w/w)	>= 0 — < 3 % (w/w)	
Water EC no.: 231-791-2	1 % (w/w)	>= 0 — < 2 % (w/w)	

HARMONISED CLASSIFICATION IN ACCORDANCE WITH THE CLASSIFICATION LABELLING AND PACKAGING REGULATION EC (NO) 1272/2008

Acute Tox. 4 (oral): H302: Harmful if swallowed.
Acute Tox. 4 (inhalation): H332: Harmful if inhaled.
Repr. 1A: H360Df: May damage the unborn child. Suspected of damaging fertility.
STOT Rep. Exp. 2: H373: May cause damage to organs through prolonged or repeated exposure.
Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.
Aquatic Acute Category 1 H400: Very toxic to aquatic life.

Specific Concentration Limits, M-Factors

SCL:
Repr. 2; H361f: C ≥ 2.5%
STOT RE 2; H373: C ≥ 0,5 %

INDUSTRY SELF-CLASSIFICATION*

Acute Tox. 4 (oral); H302: Harmful if swallowed.

Acute Tox. 4 (inhalation); H332: Harmful if inhaled.
Repro. 1A; H360Df: May damage the unborn child. Suspected of damaging fertility.
Repro. 1A; H362: May cause harm to breast-fed children.
Carc. 2; H351: Suspected of causing cancer.
STOT RE1; H372: Causes damage to organs through prolonged or repeated exposure.
Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.
Aquatic Acute 1; H400: Very toxic to aquatic life.
Specific Concentration Limits, M-Factors

SCL:
Repr. 2; H361f: C ≥ 2.5%
STOT RE 1; H372: C ≥ 0.5%

M-Factor:
Aquatic Acute 1: 1
Aquatic Chronic 1: 1

CLP LABELLING

Signal word: Danger

Hazard pictograms:
GHS07: exclamation mark

GHS08: health hazard

GHS09: environment

Hazard statements:

H410	Very toxic to aquatic life with long lasting effects.
H360Df	May damage the unborn child. Suspected of damaging fertility.
H362	May cause harm to breast-fed children.
H332	Harmful if inhaled.
H302	Harmful if swallowed.
H372	Causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion.
H351	Suspected of causing cancer.

Notes:

Industry self-classification explanation*

Fatty acids, C16-C18, lead salts are included in Regulation (EC) No 1272/2008 Annex VI Table 3.1 under the entry "lead compounds with the exception of those specified elsewhere in this Annex (Index No 082-001-00-6). As such this entry is legally binding and must there be cited on both the label and SDS. However, for hazard classes not covered by Annex I, the manufacturer or importer is required to self-classify the substance in accordance with the criteria described in the guidance to the DSD. Thus Carc. 2; H351: Suspected of causing cancer is added. In addition, in exceptional circumstances it is possible that potentially harmful levels of lead may be transmitted in breast milk of mothers exposed to lead to nursing infants. It is therefore proposed that an additional hazard statement "H362: May cause harm to breast-fed children" also be applied for Repro. 1A.

Endpoints marked by a * in Annex VI, the classification listed constitutes a minimum classification. Therefore based upon supporting data referenced in the REACH registration dossier STOT-RE 2 is changed to STOT-RE 1 as human evidence exists for repeat dose effects on CNS, kidney and haematological (blood) systems. It is proposed that the existing SCL of ≥0.5% is maintained for STOT-RE1.

It should be noted that Industry believes that data are available that support removal of classification Acute Tox. 4 (oral); H302: Harmful if swallowed. Acute Tox. 4 (inhalation); H332: Harmful if inhaled. However, this can only be undertaken by making a proposal to ECHA to be discussed at RAC and the classification officially changed via an Adaption to Technical Progress.

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