

Helsinki, 19.12.2011

Inclusion of Substances of Very High Concern in the Candidate List

(Decision of the European Chemicals Agency)

<p>Owner: Jukka Malm</p> <p>Validity: Indefinite</p> <p>Classification: Public</p>	<p>Distribution:</p> <p>Director of Regulatory Affairs Quality Manager HoU D.2 Executive office</p>
---	--

Whereas

(1) Pursuant to Article 59 of 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) the European Chemicals Agency received from Member States fourteen Annex XV dossiers for substances which in their opinion meet the criteria of Substances of Very High Concern set out in Article 57 of REACH and the European Chemicals Agency itself prepared six dossiers in the format set out in Annex XV at the request of the European Commission.

(2) The Agency invited all interested parties and Member States to submit comments on the Annex XV dossiers.

(3) The public commenting period for all substances ended on 13 October 2011.

(4) The Agency received no comments on the identification as Substances of Very High Concern for the following substances:

- formaldehyde, oligomeric reaction products with aniline,
- bis(2-methoxyethyl) phthalate,
- 2-methoxyaniline,
- bis(2-methoxyethyl) ether,
- phenolphthalein,
- lead diazide, lead azide,
- lead styphnate and
- lead dipicrate.

Pursuant to Article 59(6) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV.

(5) The Agency received comments on the identification as a Substance of Very High Concern for the following substances:

- dichromium tris(chromate),
- potassium hydroxyoctaoxidizincatedichromate,
- pentazinc chromate octahydroxide,
- aluminosilicate refractory ceramic fibres¹,
- zirconia aluminosilicate refractory ceramic fibres²,
- 4-(1,1,3,3-tetramethylbutyl)phenol,

¹ Aluminosilicate Refractory Ceramic Fibres

are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions:

a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges; b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm); c) alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18% by weight.

² Zirconia Aluminosilicate Refractory Ceramic Fibres

are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions:

a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges; b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm); c) alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18% by weight.

- 1,2-dichloroethane,
- arsenic acid,
- calcium arsenate,
- trilead diarsenate,
- N,N-dimethylacetamide and
- 2,2'-dichloro-4,4'-methylenedianiline.

Pursuant to Article 59(7) of REACH these substances were referred to the Member State Committee.

(6) The Member State Committee unanimously agreed via written procedure, which closed on 24 November 2011, and at its 21st meeting (7-9 December 2011) that

- dichromium tris(chromate),
- potassium hydroxyoctaoxidizincatedichromate,
- pentazinc chromate octahydroxide,
- aluminosilicate refractory ceramic fibres¹,
- zirconia aluminosilicate refractory ceramic fibres²,
- 4-(1,1,3,3-tetramethylbutyl)phenol,
- 1,2-dichloroethane,
- arsenic acid,
- calcium arsenate,
- trilead diarsenate,
- N,N-dimethylacetamide and
- 2,2'-dichloro-4,4'-methylenedianiline

meet the criteria for identification as Substances of Very High Concern.

Pursuant to Article 59(8) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV.

THE EUROPEAN CHEMICALS AGENCY

HAS DECIDED THE FOLLOWING:

- 1. Pursuant to Article 59(6) of REACH the following substances shall be included on 19 December 2011 in the Candidate List of substances for eventual inclusion in Annex XIV.**

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
Formaldehyde, oligomeric reaction products with aniline	500-036-1	25214-70-4	Art. 57 (a), carcinogenic
Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	Art. 57 (c), toxic for reproduction
2-Methoxyaniline; o-Anisidine	201-963-1	90-04-0	Art. 57 (a), carcinogenic
Bis(2-methoxyethyl) ether	203-924-4	111-96-6	Art. 57 (c), toxic for reproduction
Phenolphthalein	201-004-7	77-09-8	Art. 57 (a), carcinogenic
Lead diazide, Lead azide	236-542-1	13424-46-9	Art. 57 (c), toxic for reproduction
Lead styphnate	239-290-0	15245-44-0	Art. 57 (c), toxic for reproduction
Lead dipicrate	229-335-2	6477-64-1	Art. 57 (c), toxic for reproduction

2. Pursuant to Article 59(8) of REACH the following substances shall be included on 19 December 2011 in the Candidate List of substances for eventual inclusion in Annex XIV.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
Dichromium tris(chromate)	246-356-2	24613-89-6	Art. 57 (a), carcinogenic
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	Art. 57 (a), carcinogenic
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	Art. 57 (a), carcinogenic
Aluminosilicate Refractory Ceramic Fibres Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges; b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm); c) alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18% by weight	-	-	Art. 57 (a), carcinogenic
Zirconia Aluminosilicate Refractory Ceramic Fibres Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium, silicon and	-	-	Art. 57 (a), carcinogenic

zirconium are the main components present (in the fibres) within variable concentration ranges; b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm); c) alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+MgO+BaO) content less or equal to 18% by weight			
4-(1,1,3,3-tetramethylbutyl)phenol,	205-426-2	140-66-9	Art. 57 (f), equivalent level of concern having probable serious effects to the environment
1,2-dichloroethane	203-458-1	107-06-2	Art. 57 (a), carcinogenic
Arsenic acid	231-901-9	7778-39-4	Art. 57 (a), carcinogenic
Calcium arsenate	231-904-5	7778-44-1	Art. 57 (a), carcinogenic
Trilead diarsenate	222-979-5	3687-31-8	Art. 57 (a) & (c), carcinogenic & toxic for reproduction
N,N-dimethylacetamide	204-826-4	127-19-5	Art. 57 (c), toxic for reproduction
2,2'-dichloro-4,4'-methylenedianiline	202-918-9	101-14-4	Art. 57 (a), carcinogenic

3. Publication

The updated Candidate List shall be published on ECHA's website on 19 December 2011.

Done at Helsinki, 19 December 2011



Jukka Malm
Director of Regulatory Affairs³

³ Mandated to sign this decision pursuant to the decision of the Executive Director ED/110/2010 delegating the powers to sign decisions to include a substance on the Candidate List for eventual inclusion in Annex XIV under Article 59(6) or Article 59(8) of the REACH Regulation to Jukka Malm, Director of Regulatory Affairs.