Inclusion of Substances of Very High Concern in the Candidate List

(Decision of the European Chemicals Agency)

Owner: Jukka Malm
Validity: Indefinite
Classification: Public

Distribution:
Director of Regulatory Affairs
Quality Manager
HoU D.2
Executive office

Helsinki, 19.12.2011
Whereas


(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 hydroxyoctaoxodizinctenedichromate,
   - pentazinc chromate octahydroxide,
   - aluminosilicate refractory ceramic fibres\(^1\),
   - zirconia aluminosilicate refractory ceramic fibres\(^2\),
   - 4-(1,1,3,3-tetramethylybutyl)phenol,

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\(^1\) 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 than two standard geometric errors of 6 or less micrometres (\(\mu m\)); c) alkaline oxide and alkali earth oxide (Na\(_2\)O+K\(_2\)O+CaO+MgO+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 than two standard geometric errors of 6 or less micrometres (\(\mu m\)); c) alkaline oxide and alkali earth oxide (Na\(_2\)O+K\(_2\)O+CaO+MgO+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 hydroxyoctaoxodizincatedichromate,
• 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.

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

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</thead>
<tbody>
<tr>
<td>Dichromium tris(chromate)</td>
<td>246-356-2</td>
<td>24613-89-6</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>Potassium hydroxyoctaoxodizincatedichromate</td>
<td>234-329-8</td>
<td>11103-86-9</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>Pentazinc chromate octahydroxide</td>
<td>256-418-0</td>
<td>49663-84-5</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>Aluminosilicate Refractory Ceramic Fibres</td>
<td>-</td>
<td>-</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>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 (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight.</td>
<td></td>
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</tr>
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<td>Zirconia Aluminosilicate Refractory Ceramic Fibres</td>
<td>-</td>
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<td>Art. 57 (a), carcinogenic</td>
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</tbody>
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| 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
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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 (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight

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<th>CAS Number</th>
<th>EC Number</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-(1,1,3,3-tetramethylbutyl)phenol</td>
<td>205-426-2</td>
<td>140-66-9</td>
<td>Art. 57 (f), equivalent level of concern having probable serious effects to the environment</td>
</tr>
<tr>
<td>1,2-dichloroethane</td>
<td>203-458-1</td>
<td>107-06-2</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>Arsenic acid</td>
<td>231-901-9</td>
<td>7778-39-4</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>231-904-5</td>
<td>7778-44-1</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
<tr>
<td>Trilead diarsenate</td>
<td>222-979-5</td>
<td>3687-31-8</td>
<td>Art. 57 (a) &amp; (c), carcinogenic &amp; toxic for reproduction</td>
</tr>
<tr>
<td>N,N-dimethylacetamide</td>
<td>204-826-4</td>
<td>127-19-5</td>
<td>Art. 57 (c), toxic for reproduction</td>
</tr>
<tr>
<td>2,2'-dichloro-4,4'-methyleneedianiline</td>
<td>202-918-9</td>
<td>101-14-4</td>
<td>Art. 57 (a), carcinogenic</td>
</tr>
</tbody>
</table>

3. **Publication**

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

Done at Helsinki, 19 December 2011

![Signature]

Jukka Malm  
Director of Regulatory Affairs

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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.