

Helsinki, 18. 12. 2012

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>
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Whereas

(1) Pursuant to Article 59(3) 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 (hereinafter referred to as 'ECHA' or 'the Agency') received from Member States seventeen dossiers in accordance with Annex XV to REACH for substances which in their opinion meet the criteria of Substances of Very High Concern (SVHCs) set out in Article 57 REACH;

(2) ECHA itself prepared thirty-seven dossiers in the format set out in Annex XV to REACH at the request of the European Commission, in accordance with Art. 59(2) REACH;

(3) On 3 September 2012 the Agency invited all interested parties and Member States to submit comments on the Annex XV dossiers, as stated in Art. 59(4 and 5) REACH;

(4) The public commenting period for all substances ended on 18 October 2012;

(5) The Agency did not receive or make any comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Diisopentylphthalate (DIPP)	210-088-4	605-50-5
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0
N-pentyl-isopentylphthalate	-	776297-69-9
1,2-Diethoxyethane	211-076-1	629-14-1
Lead cyanamidate	244-073-9	20837-86-9
Lead dinitrate	233-245-9	10099-74-8
[phthalato(2-)]dioxotrilead	273-688-5	69011-06-9
Lead oxide sulfate	234-853-7	12036-76-9
Tetralead trioxide sulphate	235-380-9	12202-17-4
Pentalead tetraoxide sulphate	235-067-7	12065-90-6
Dioxobis(stearato)trilead	235-702-8	12578-12-0
Trilead dioxide phosphonate	235-252-2	12141-20-7
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7
Fatty acids, C16-18, lead salts	292-966-7	91031-62-8
Tetraethyllead	201-075-4	78-00-2
Acetic acid, lead salt, basic	257-175-3	51404-69-4
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8
Dimethyl sulphate	201-058-1	77-78-1
Diethyl sulphate	200-589-6	64-67-5
Dinoseb (6-sec-butyl-2,4-dinitrophenol)	201-861-7	88-85-7
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2
N-methylacetamide	201-182-6	79-16-3
Furan	203-727-3	110-00-9
4,4'-oxydianiline and its salts	202-977-0	101-80-4
4-methyl-m-phenylenediamine (toluene-2,4-diamine)	202-453-1	95-80-7
Biphenyl-4-ylamine	202-177-1	92-67-1
o-Aminoazotoluene (4-o-Tolylazo-o-toluidine)	202-591-2	97-56-3
o-Toluidine	202-429-0	95-53-4
6-methoxy-m-toluidine (p-cresidine)	204-419-1	120-71-8

4,4'-Methylenedi- <i>o</i> -toluidine	212-658-8	838-88-0
4-Aminoazobenzene	200-453-6	60-09-3

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

(6) The Agency received or made comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	204-650-8	123-77-3
Heptacosafuorotetradecanoic acid	206-803-4	376-06-7
Henicosafuoroundecanoic acid	218-165-4	2058-94-8
Pentacosafuorotridecanoic acid	276-745-2	72629-94-8
Tricosafuorododecanoic acid	206-203-2	307-55-1
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	-	-
4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-
Methoxyacetic acid	210-894-6	625-45-6
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3], [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE)	214-604-9	1163-19-5
Dibutyltin dichloride (DBTC)	211-670-0	683-18-1
N,N-dimethylformamide	200-679-5	68-12-2
Lead monoxide (Lead oxide)	215-267-0	1317-36-8
Orange lead (Lead tetroxide)	215-235-6	1314-41-6
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5
Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6
Lead titanium trioxide	235-038-9	12060-00-3
Lead titanium zirconium oxide	235-727-4	12626-81-2
Silicic acid, lead salt	234-363-3	11120-22-2
Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped [with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]	272-271-5	68784-75-8
1-bromopropane (n-propyl bromide)	203-445-0	106-94-5
Methyloxirane (Propylene oxide)	200-879-2	75-56-9

Thus, pursuant to Article 59(7) REACH the dossiers related to these substances were referred to the Member State Committee (MSC).

(7) MSC unanimously agreed either via written procedure, which closed on 29 November 2012, or at its 27th meeting (10-13 December 2012) that the following substances meet criteria set out in Article 57 REACH for identification as SVHCs:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	204-650-8	123-77-3
Heptacosafuorotetradecanoic acid	206-803-4	376-06-7
Henicosafuoroundecanoic acid	218-165-4	2058-94-8
Pentacosafuorotridecanoic acid	276-745-2	72629-94-8
Tricosafuorododecanoic acid	206-203-2	307-55-1
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	-	-
4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-
Methoxyacetic acid	210-894-6	625-45-6
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE)	214-604-9	1163-19-5
Dibutyltin dichloride (DBTC)	211-670-0	683-18-1
N,N-dimethylformamide	200-679-5	68-12-2
Lead monoxide (Lead oxide)	215-267-0	1317-36-8
Orange lead (Lead tetroxide)	215-235-6	1314-41-6
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5
Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6
Lead titanium trioxide	235-038-9	12060-00-3
Lead titanium zirconium oxide	235-727-4	12626-81-2
Silicic acid, lead salt	234-363-3	11120-22-2
Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped [with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]	272-271-5	68784-75-8

1-bromopropane (n-propyl bromide)	203-445-0	106-94-5
Methyloxirane (Propylene oxide)	200-879-2	75-56-9

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

(8) In accordance with Article 59(10) REACH, the Candidate List shall be published on ECHA's website.

THE EUROPEAN CHEMICALS AGENCY

HAS DECIDED THE FOLLOWING:

- Pursuant to Article 59(6) REACH the following substances shall be included on 19 December 2012 in the Candidate List for eventual inclusion in Annex XIV to REACH.**

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR SVHC IDENTIFICATION
Diisopentylphthalate (DIPP)	210-088-4	605-50-5	Toxic for reproduction (Art 57 (c))
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	Toxic for reproduction (Article 57 (c))
N-pentyl-isopentylphthalate	-	776297-69-9	Toxic for reproduction (Article 57 (c))
1,2-Diethoxyethane	211-076-1	629-14-1	Toxic for reproduction (Article 57 (c))
Lead cyanamidate	244-073-9	20837-86-9	Toxic for reproduction (Article 57 (c))
Lead dinitrate	233-245-9	10099-74-8	Toxic for reproduction (Article 57 (c))
[phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	Toxic for reproduction (Article 57 (c))
Lead oxide sulfate	234-853-7	12036-76-9	Toxic for reproduction (Article 57 (c))
Tetralead trioxide sulphate	235-380-9	12202-17-4	Toxic for reproduction (Article 57 (c))
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	Toxic for reproduction (Article 57 (c))
Dioxobis(stearato)trilead	235-702-8	12578-12-0	Toxic for reproduction (Article 57 (c))
Trilead dioxide phosphonate	235-252-2	12141-20-7	Toxic for reproduction (Article 57 (c))
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	Toxic for reproduction (Article 57 (c))
Fatty acids, C16-18, lead salts	292-966-7	91031-62-8	Toxic for reproduction (Article 57 (c))
Tetraethyllead	201-075-4	78-00-2	Toxic for reproduction (Article 57 (c))
Acetic acid, lead salt, basic	257-175-3	51404-69-4	Toxic for reproduction (Article 57 (c))
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	Toxic for reproduction (Article 57 (c))
Dimethyl sulphate	201-058-1	77-78-1	Carcinogenic (Article 57(a))
Diethyl sulphate	200-589-6	64-67-5	Carcinogenic (Article 57(a)), Mutagenic (Article 57(b))
Dinoseb (6-sec-butyl-2,4-dinitrophenol)	201-861-7	88-85-7	Toxic for reproduction (Article 57 (c))
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2	Toxic for reproduction (Article 57 (c))
N-methylacetamide	201-182-6	79-16-3	Toxic for reproduction

			(Article 57 (c))
Furan	203-727-3	110-00-9	Carcinogenic (Article 57(a))
4,4'-oxydianiline and its salts	202-977-0	101-80-4	Carcinogenic (Article 57(a)), Mutagenic (Article 57(b))
4-methyl- <i>m</i> -phenylenediamine (toluene-2,4-diamine)	202-453-1	95-80-7	Carcinogenic (Article 57(a))
Biphenyl-4-ylamine	202-177-1	92-67-1	Carcinogenic (Article 57(a))
<i>o</i> -Aminoazotoluene (4- <i>o</i> -Tolylazo- <i>o</i> -toluidine)	202-591-2	97-56-3	Carcinogenic (Article 57(a))
<i>o</i> -Toluidine	202-429-0	95-53-4	Carcinogenic (Article 57(a))
6-methoxy- <i>m</i> -toluidine (p-cresidine)	204-419-1	120-71-8	Carcinogenic (Article 57(a))
4,4'-Methylenedi- <i>o</i> -toluidine	212-658-8	838-88-0	Carcinogenic (Article 57(a))
4-Aminoazobenzene	200-453-6	60-09-3	Carcinogenic (Article 57(a))

2. Pursuant to Article 59(8) REACH the following substances shall be included on 19 December 2012 in the Candidate List for eventual inclusion in Annex XIV to REACH.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR SVHC IDENTIFICATION
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	204-650-8	123-77-3	Equivalent level of concern - probable serious effects to human health (Article 57 (f))
Heptacosafuorotetradecanoic acid	206-803-4	376-06-7	vPvB (Article 57 (e))
Henicosafuoroundecanoic acid	218-165-4	2058-94-8	vPvB (Article 57 (e))
Pentacosafuorotridecanoic acid	276-745-2	72629-94-8	vPvB (Article 57 (e))
Tricosafuorododecanoic acid	206-203-2	307-55-1	vPvB (Article 57 (e))
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated <i>[covering well-defined substances and UVCB substances, polymers and homologues]</i>	-	-	Equivalent level of concern - probable serious effects to the environment (Article 57 (f))
4-Nonylphenol, branched and linear <i>[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]</i>	-	-	Equivalent level of concern - probable serious effects to the environment (Article 57 (f))
Methoxyacetic acid	210-894-6	625-45-6	Toxic for reproduction (Article 57 (c))
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] <i>[The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]</i>	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3	Equivalent level of concern - probable serious effects to human health (Article 57 (f))
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] <i>[The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]</i>	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	Equivalent level of concern - probable serious effects to human health (Article 57 (f))
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE)	214-604-9	1163-19-5	PBT (Art.57 (d)), vPvB (Article 57 (e))

Dibutyltin dichloride (DBTC)	211-670-0	683-18-1	Toxic for reproduction (Article 57 (c))
N,N-dimethylformamide	200-679-5	68-12-2	Toxic for reproduction (Article 57 (c))
Lead monoxide (Lead oxide)	215-267-0	1317-36-8	Toxic for reproduction (Article 57 (c))
Orange lead (Lead tetroxide)	215-235-6	1314-41-6	Toxic for reproduction (Article 57 (c))
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	Toxic for reproduction (Article 57 (c))
Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6	Toxic for reproduction (Article 57 (c))
Lead titanium trioxide	235-038-9	12060-00-3	Toxic for reproduction (Article 57 (c))
Lead titanium zirconium oxide	235-727-4	12626-81-2	Toxic for reproduction (Article 57 (c))
Silicic acid, lead salt	234-363-3	11120-22-2	Toxic for reproduction (Article 57 (c))
Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped [with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]	272-271-5	68784-75-8	Toxic for reproduction (Article 57 (c))
1-bromopropane (n-propyl bromide)	203-445-0	106-94-5	Toxic for reproduction (Article 57 (c))
Methyloxirane (Propylene oxide)	200-879-2	75-56-9	Carcinogenic (Article 57(a)), Mutagenic (Article 57(b))

3. Publication

The updated Candidate List shall be published on ECHA's website on 19 December 2012.

Done at Helsinki, 18. 12. 2012


Jukka Malm
Director of Regulatory Affairs¹

¹ Mandated to sign this decision pursuant to the decision by the Executive Director ED/110/2010 *Delegation of the power to sign certain science-based regulatory decisions and communications*, 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) REACH to Jukka Malm, Director of Regulatory Affairs.