

Helsinki, 12. 12. 2014

Inclusion of Substances of Very High Concern in the Candidate List for eventual inclusion in Annex XIV

(Decision by the Executive Director)

<p>Owner: Jukka Malm Activity/ Process: Candidate List update Validity: Indefinite Classification: Public</p>	<p>Distribution: Deputy Executive Director Quality Manager HoU D.2 Executive Office</p>
---	--

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 ten 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 of REACH.

(2) On 1 September 2014, the Agency invited all interested parties to submit comments on the Annex XV dossiers, as stated in Article 59(4) REACH.

(3) The public commenting period for all substances ended on 16 October 2014.

(4) In accordance with Article 59(5) REACH, the deadline for Member States or the Agency to comment on the identification of the substances as SVHCs was 31 October 2014.

(5) The Agency received comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Cadmium fluoride	232-222-0	7790-79-6
Cadmium sulphate	233-331-6	10124-36-4; 31119-53-6
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Dibutyl phthalate (DBP)	201-557-4	84-74-2
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1
reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-

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

(7) The MSC unanimously agreed via written procedure, which closed on 27 November 2014, and at its 39th meeting (8-11 December 2014) that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHCs:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Cadmium fluoride	232-222-0	7790-79-6
Cadmium sulphate	233-331-6	10124-36-4; 31119-53-6
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-	247-384-8	25973-55-1

328)		
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1
reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-

(8) Therefore, pursuant to Article 59(8) of REACH the Agency shall now include these substances in the Candidate List.

(9) The MSC also unanimously agreed at its 39th meeting that the following substance meets the criteria set out in Article 57(f) of REACH for identification as SVHC on the basis of an equivalent level of concern having probable serious effects to the environment.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7

(10) As the substance bis(2-ethylhexyl) phthalate (DEHP) is already listed on the Candidate List, this entry shall now be updated to reflect the additional reason for inclusion, i.e. that it demonstrates an equivalent level of concern having probable serious effects to the environment in accordance with Article 57(f) of REACH.

(11) Therefore, pursuant to Article 59(8) of REACH the Agency shall now update the entry for bis(2-ethylhexyl) phthalate (DEHP).

(12) The Member State Committee at its 39th meeting did not unanimously agree that the following substances meet the criteria set out in Article 57(f) of REACH, i.e. that they demonstrate an equivalent level of concern having probable serious effects to human health:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Dibutyl phthalate (DBP)	201-557-4	84-74-2
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5

(13) The entries for these substances in the Candidate List shall therefore not be updated on this ground.

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

I HAVE DECIDED THE FOLLOWING:

- 1. Pursuant to Article 59(8) of REACH the following substances shall be included on 17 December 2014 in the Candidate List for eventual inclusion in Annex XIV to REACH.**

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
Cadmium fluoride	232-222-0	7790-79-6	Carcinogenic (Article 57 a); Mutagenic (Article 57 b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium sulphate	233-331-6	10124-36-4; 31119-53-6	Carcinogenic (Article 57 a); Mutagenic (Article 57 b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	PBT (Article 57 d); vPvB (Article 57 e)
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	PBT (Article 57 d); vPvB (Article 57 e)
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1	Toxic for reproduction (Article 57 c)
reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-	Toxic for reproduction (Article 57 c)

- 2. Pursuant to Article 59(8) of REACH the existing entry for following substance shall be updated on 17 December 2014 in the Candidate List for eventual inclusion in Annex XIV to REACH.**

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Equivalent level of concern having probable serious effects to the environment (Article 57 f)

3. Publication

The updated Candidate List shall be published on ECHA's website on 17 December 2014.

Done at Helsinki,

12. 12. 2014



Jukka Malm¹
Deputy Executive Director

¹ Mandated to sign this decision pursuant to the decision of the Executive Director ED/05/2014 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, Deputy Executive Director.