

Helsinki, 12. 12. 2013

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

**(Decision of the European Chemicals Agency)**

<p><b>Owner: Jukka Malm</b></p> <p><b>Validity: Indefinite</b></p> <p><b>Classification: Public</b></p>	<p><b>Distribution:</b></p> <p><b>Director of Regulatory Affairs</b> <b>Quality Manager</b> <b>HoU D.2</b> <b>Executive office</b></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 seven 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 2 September 2013, the Agency invited all interested parties to submit comments on the Annex XV dossiers, as stated in Article 59(4) and 59(5) REACH.

(3) The public commenting period for all substances ended on 17 October 2013.

(4) In accordance with Article 59(5) REACH, the deadline for Member States or the Agency to comment was 4 November 2013.

(5) The Agency received no comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4	573-58-0
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3	1937-37-7
Imidazolidine-2-thione (2-imidazoline-2-thiol)	202-506-9	96-45-7
Lead di(acetate)	206-104-4	301-04-2
Trixylyl phosphate	246-677-8	25155-23-1

(5) Thus, pursuant to Article 59(6) the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV (hereinafter referred to as the Candidate List).

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

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Cadmium sulphide	215-147-8	1306-23-6
Dihexyl phthalate	201-559-5	84-75-3

Thus, pursuant to Article 59(7) of REACH the dossiers related to these substances were referred to the Member State Committee (MSC) for further agreement seeking on 18 November 2013.

(7) The MSC unanimously agreed via written procedure, which closed on 28 November 2013, that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHCs:

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>
Cadmium sulphide	215-147-8	1306-23-6
Dihexyl phthalate	201-559-5	84-75-3

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

(9) 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:**

- 1. Pursuant to Article 59(6) and (8) of REACH the following substances shall be included on 16 December 2013 in the Candidate List for eventual inclusion in Annex XIV to REACH.**

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>	<b>REASON FOR INCLUSION</b>
Cadmium sulphide	215-147-8	1306-23-6	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4	573-58-0	Carcinogenic (Article 57a)
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3	1937-37-7	Carcinogenic (Article 57a)
Dihexyl phthalate	201-559-5	84-75-3	Toxic for reproduction (Article 57 c)
Imidazolidine-2-thione (2-imidazoline-2-thiol)	202-506-9	96-45-7	Toxic for reproduction (Article 57 c)
Lead di(acetate)	206-104-4	301-04-2	Toxic for reproduction (Article 57 c)
Trixylyl phosphate	246-677-8	25155-23-1	Toxic for reproduction (Article 57 c)

**2. Publication**

The updated Candidate List shall be published on ECHA's website on 16 December 2013.

Done at Helsinki, 12. 12. 2013

  
Jukka Malm  
Director of Regulatory Affairs<sup>1</sup>

<sup>1</sup>Mandated to sign this decision pursuant to the decision of the Executive Director ED/108/2013.