

Helsinki, 20.06.2018

Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV

(Decision of the European Chemicals Agency)

<p>Owner: Jukka Malm Activity/Process: 03.02 Identification of SVHC Validity: Indefinite</p>	<p>Distribution: Executive Director Deputy Executive Director Director D Quality Manager HoU D.2 ECHANet</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 'The Agency') received from Member States six 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) The Agency itself prepared two dossiers according to the provisions set out in Annex XV to REACH at the request of the European Commission, in accordance with Article 59(2) of REACH.
- 3) On 08 March 2018, the Agency invited all interested parties to submit comments on the Annex XV dossiers, as stated in Article 59(4) of REACH.
- 4) The public commenting period for all substances ended on 23 April 2018.
- 5) In accordance with Article 59(5) of REACH, the deadline for Member States or the Agency to comment on the identification of the substances as SVHCs was 07 May 2018.
- 6) The Agency received comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Octamethylcyclotetrasiloxane	209-136-7	556-67-2
Decamethylcyclopentasiloxane	208-764-9	541-02-6
Dodecamethylcyclohexasiloxane	208-762-8	540-97-6
Lead	231-100-4	7439-92-1
Disodium octaborate	234-541-0	12008-41-2
Benzo[ghi]perylene	205-883-8	191-24-2
Terphenyl hydrogenated	262-967-7	61788-32-7
Ethylenediamine	203-468-6	107-15-3

- 7) Thus, pursuant to Article 59(7) of REACH the dossiers related to these substances were referred to the Member State Committee (MSC).
- 8) The MSC unanimously agreed via written procedure, which closed on 01 June 2018 that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHC:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Disodium octaborate	234-541-0	12008-41-2
Benzo[ghi]perylene	205-883-8	191-24-2
Terphenyl hydrogenated	262-967-7	61788-32-7
Ethylenediamine	203-468-6	107-15-3

- 9) Therefore, pursuant to Article 59(8) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV to REACH.
- 10) The Member State Committee at its 60th meeting unanimously agreed that the following substances meet the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Octamethylcyclotetrasiloxane	209-136-7	556-67-2
Decamethylcyclopentasiloxane	208-764-9	541-02-6
Dodecamethylcyclohexasiloxane	208-762-8	540-97-6
Lead	231-100-4	7439-92-1

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

12) Pursuant to Article 59(9) of REACH the European Commission was required to take a decision on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Benzene-1,2,4-tricarboxylic acid 1,2 anhydride	209-008-0	552-30-7
Dicyclohexyl phthalate	201-545-9	84-61-7

13) As a result the Commission adopted Implementing Decision (EU) 2018/594 of 13 April 2018 identifying benzene-1,2,4-tricarboxylic acid 1,2 anhydride as a substance having respiratory sensitising properties whose effects to human health give rise to an equivalent level of concern according to Article 57(f) of REACH.

14) The Commission also adopted Implementing Decision (EU) 2018/636 of 17 April 2018 identifying dicyclohexyl phthalate as a substance having toxic for reproduction properties according to Article 57(c) of REACH and endocrine disrupting properties whose effects to human health give rise to an equivalent level of concern according to Article 57(f) of REACH.

15) Therefore, pursuant to Article 59(9) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV to REACH.

16) In accordance with Article 59(10) of REACH, the Candidate List shall be accordingly updated and published on the Agency's website.

I HAVE DECIDED THE FOLLOWING:

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

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Octamethylcyclotetrasiloxane	209-136-7	556-67-2	PBT (Article 57d) vPvB (Article 57e)
Decamethylcyclopentasiloxane	208-764-9	541-02-6	PBT (Article 57d) vPvB (Article 57e)
Dodecamethylcyclohexasiloxane	208-762-8	540-97-6	PBT (Article 57d) vPvB (Article 57e)
Lead	231-100-4	7439-92-1	Toxic for reproduction (Article 57c)
Disodium octaborate	234-541-0	12008-41-2	Toxic for reproduction (Article 57c)
Benzo[ghi]perylene	205-883-8	191-24-2	PBT (Article 57d) vPvB (Article 57e)
Terphenyl hydrogenated	262-967-7	61788-32-7	vPvB (Article 57e)
Ethylenediamine	203-468-6	107-15-3	Respiratory sensitising properties (Article 57(f) - human health)

2. Pursuant to Article 59(9) of REACH the following substances shall be included in the Candidate List for eventual inclusion in Annex XIV to REACH.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Benzene-1,2,4-tricarboxylic acid 1,2 anhydride	209-008-0	552-30-7	Respiratory sensitising properties (Article 57(f) - human health)
Dicyclohexyl phthalate	201-545-9	84-61-7	Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - human health)

3. Pursuant to Article 59(10) of REACH the Agency shall publish and update on its website the Candidate List for eventual inclusion in Annex XIV to REACH with the following entries:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Octamethylcyclotetrasiloxane	209-136-7	556-67-2	PBT (Article 57d) vPvB (Article 57e)
Decamethylcyclopentasiloxane	208-764-9	541-02-6	PBT (Article 57d) vPvB (Article 57e)
Dodecamethylcyclohexasiloxane	208-762-8	540-97-6	PBT (Article 57d) vPvB (Article 57e)
Lead	231-100-4	7439-92-1	Toxic for reproduction (Article 57c)
Disodium octaborate	234-541-0	12008-41-2	Toxic for reproduction (Article 57c)
Benzo[ghi]perylene	205-883-8	191-24-2	PBT (Article 57d) vPvB (Article 57e)
Terphenyl hydrogenated	262-967-7	61788-32-7	vPvB (Article 57e)
Ethylenediamine	203-468-6	107-15-3	Respiratory sensitising properties (Article 57(f) - human health)
Benzene-1,2,4-tricarboxylic acid 1,2 anhydride	209-008-0	552-30-7	Respiratory sensitising properties (Article 57(f) - human health)
Dicyclohexyl phthalate	201-545-9	84-61-7	Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) – human health)

3. Publication

The updated Candidate List shall be published on the Agency's website on 27 June 2018. This decision shall take effect from 27 June 2018.

(e-signed)

Jukka Malm¹
Deputy Executive Director²

¹ Mandated to sign this decision pursuant to the decision of the Executive Director ED/58/2018 delegating the power 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.

² As this is an electronic document, it is not physically signed. This communication has been approved according to the Agency's internal decision-approval process.