

Helsinki, 16 December 2022

## **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: Mike Rasenberg</b></p> <p><b>Activity/Process: 03.02</b></p> <p><b>Identification of SVHC</b></p> <p><b>Validity: Indefinite</b></p>	<p><b>Distribution:</b></p> <p><b>Executive Director</b></p> <p><b>Deputy Executive Director</b></p> <p><b>Director C</b></p> <p><b>Quality Manager</b></p> <p><b>HoU C3</b></p> <p><b>ECHANet</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 'The Agency') received from Member States nine Annex XV dossiers 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 02 September 2022, the Agency invited all interested parties to submit comments on the Annex XV dossiers, as stated in Article 59(4) of REACH.
- (3) The interested party commenting period for all substances ended on 17 October 2022.
- (4) 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 02 November 2022.
- (5) The Agency did not receive or make any comments on the identification as SVHC for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Barium diboron tetraoxide	237-222-4	13701-59-2
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9	79-94-7

- (6) Therefore, these substances are identified as substances of very high concern for the reasons set out in the relevant support documents of these substances. Pursuant to Article 59(6) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV to REACH.
- (7) The Agency received comments on the identification as SVHC for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluoroheptanoic acid and its salts	-	-
1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]	253-692-3	37853-59-1
Melamine	203-615-4	108-78-1
Isobutyl 4-hydroxybenzoate	224-208-8	4247-02-3
bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	-	-
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	473-390-7	-
4,4'-sulphonyldiphenol	201-250-5	80-09-1

- (8) Thus, pursuant to Article 59(7) of REACH the dossiers related to these substances were referred to the Member State Committee (MSC).
- (9) The MSC unanimously agreed via written procedure, which closed on 28 November 2022, that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHC.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluoroheptanoic acid and its salts	-	-
1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]	253-692-3	37853-59-1

Isobutyl 4-hydroxybenzoate	224-208-8	4247-02-3
bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	-	-
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	473-390-7	-
4,4'-sulphonyldiphenol	201-250-5	80-09-1

(10) Therefore, these substances are identified as substances of very high concern for the reasons set out in the relevant support documents of these substances. 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.

(11) The Member State Committee at its 80<sup>th</sup> meeting unanimously agreed that the following substance meets the criteria set out in Article 57 of REACH:

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>
Melamine	203-615-4	108-78-1

(12) Therefore, this substance is identified as a substance of very high concern for the reasons set out in the relevant support document of this substance. Pursuant to Article 59(8) of REACH the Agency shall now include this substance in the Candidate List for eventual inclusion in Annex XIV to REACH.

**I HAVE DECIDED THE FOLLOWING:****1. The following substances are identified as substances of very high concern meeting the criteria under Article 57 of REACH:**

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>	<b>INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57</b>
Barium diboron tetraoxide	237-222-4	13701-59-2	Toxic for reproduction (Article 57c)
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9	79-94-7	Carcinogenic (Article 57a)
Perfluoroheptanoic acid and its salts	-	-	Toxic for reproduction (Article 57c); PBT (Article 57d); vPvB (Article 57e); Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health); Equivalent level of concern having probable serious effects to the environment (Article 57(f) - environment)
1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]	253-692-3	37853-59-1	vPvB (Article 57e)
Melamine	203-615-4	108-78-1	Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health) Equivalent level of concern having probable serious effects to the environment (Article 57(f) - environment)
Isobutyl 4-hydroxybenzoate	224-208-8	4247-02-3	Endocrine disrupting properties (Article 57(f) - human health)
bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	-	-	vPvB (Article 57e)
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	473-390-7	-	vPvB (Article 57e)
4,4'-sulphonyldiphenol	201-250-5	80-09-1	Toxic for reproduction (Article 57c);

			Endocrine disrupting properties (Article 57(f) – environment); Endocrine disrupting properties (Article 57(f) – human health)
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**2. Under Articles 59(6) and 59(8) of REACH the substances referred to in paragraph 1 above with the indications provided therein shall be included in the Candidate List for eventual inclusion in Annex XIV to REACH.**

**3. Pursuant to Article 59(10) of REACH the Agency shall on 17 January 2023 publish and update on its website the Candidate List for eventual inclusion in Annex XIV to REACH with the entries referred to in paragraph 1 above.**

#### **4. Entry into effect**

This decision shall take effect from 17 January 2023.

*(e-signed)*

Mike Rasenberg<sup>1</sup>  
Director of Hazard Assessment<sup>2</sup>

<sup>1</sup> Mandated to sign this decision in accordance with ECHA's internal process.

<sup>2</sup> 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.