

Helsinki, 16.01.2020

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: Christel Schilliger-Musset Activity/Process: 03.02 Identification of SVHC Validity: Indefinite</p>	<p>Distribution: Executive Director Deputy Executive Director Director C Quality Manager HoU C.3 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 four 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 03 September 2019, the Agency invited all interested parties to submit comments on the Annex XV dossiers, as stated in Article 59(4) of REACH.
- 3) The public commenting period for all substances ended on 18 October 2019.
- 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 04 November 2019.
- 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
Diisohexyl phthalate	276-090-2	71850-09-4
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5

- 6) Therefore, these substances are identified as substances of very high concern. 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 substance:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluorobutane sulfonic acid (PFBS) and its salts	-	-

- 8) Thus, pursuant to Article 59(7) of REACH the dossier related to this substance was referred to the Member State Committee (MSC).
- 9) The Member State Committee at its 67th meeting unanimously agreed that the following substance meets the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluorobutane sulfonic acid (PFBS) and its salts	-	-

- 10) Therefore, this substance is identified as a substance of very high concern. 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:**

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Diisohexyl phthalate	276-090-2	71850-09-4	Toxic for reproduction (Article 57c)
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	Toxic for reproduction (Article 57c)
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	Toxic for reproduction (Article 57c)
Perfluorobutane sulfonic acid (PFBS) and its salts	-	-	Equivalent level of concern having probable serious effects to the environment (Article 57(f) - environment) Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health)

The following remark is added for perfluorobutane sulfonic acid (PFBS) and its salts:

"The combined intrinsic properties justifying the inclusion as a substance for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water and soil, high potential for long-range transport, and difficulty of remediation and water purification as well as moderate bioaccumulation in humans. The observed probable serious effects for human health and the environment are thyroid hormonal disturbances and reproductive toxicity seen in rodents, and effects on liver, kidney and haematological system in rats, hormonal disturbances and effects on reproduction in marine medaka fish and effects on expression of hormone receptors in tadpoles. Together, these elements lead to a very high potential for irreversible effects."

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 16 January 2020 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 16 January 2020.

(e-signed)

Christel Schilliger-Musset¹
Director of Hazard Assessment²

¹ Mandated to sign this decision in accordance with ECHA's internal process.

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.