

Helsinki, 04.07.2019

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 three 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 13 March 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 29 April 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 13 May 2019.
- 5) The Agency did not receive or make any comments on the identification as SVHC for the following substance:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
2-methoxyethyl acetate	203-772-9	110-49-6

- 6) Therefore, pursuant to Article 59(6) of REACH the Agency shall now include this substance in the Candidate List for eventual inclusion in Annex XIV to REACH.
- 7) The Agency received comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)	-	-
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (<i>covering any of their individual isomers and combinations thereof</i>)	-	-

- 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 Member State Committee at its 65th meeting unanimously agreed that the following substances meet the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)	-	-
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (<i>covering any of their individual isomers and combinations thereof</i>)	-	-

- 10) 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.
- 11) Pursuant to Article 59(9) of REACH the European Commission was required to take a decision on the identification as SVHC for the following substance:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
4-tert-butylphenol	202-679-0	98-54-4

- 12) As a result the Commission adopted Implementing Decision (EU) 2019/1194 of 05 July 2019 identifying 4-tert-butylphenol as a substance having endocrine disrupting properties whose probable serious effects on the environment give rise to an equivalent level of concern according to Article 57(f) of REACH.
- 13) Therefore, pursuant to Article 59(9) and (10) of REACH the Agency shall now include this substance in the Candidate List for eventual inclusion in Annex XIV to REACH.
- 14) 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(6) of REACH the following substance 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
2-methoxyethyl acetate	203-772-9	110-49-6	Toxic for reproduction (Article 57c)

- 2. 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
Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)	-	-	Endocrine disrupting properties (Article 57(f) - environment)
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (<i>covering any of their individual isomers and combinations thereof</i>)	-	-	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 to be added to the entry for 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (*covering any of their individual isomers and combinations thereof*):

"The combined intrinsic properties justifying the inclusion for the Member State Committee 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:

Persistence, mobility, potential for long-range transport, observed adverse effects (at least the following probable effects for human health: effects on the liver, the kidney, and the haematological and immune systems and effects on development; at least the following probable effects for the environment: population relevant effects on birds and mammals); as well as low adsorption potential and high water solubility rendering the substance fully bioavailable for uptake via (drinking) water. Together, these elements lead to a very high potential for irreversible effects."

3. Pursuant to Article 59(9) of REACH the following substance 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
4-tert-butylphenol	202-679-0	98-54-4	Endocrine disrupting properties (Article 57(f) – environment)

4. 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
2-methoxyethyl acetate	203-772-9	110-49-6	Toxic for reproduction (Article 57c)
Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)			Endocrine disrupting properties (Article 57(f) – environment)
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides <i>(covering any of their individual isomers and combinations thereof)</i>	-	-	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)
4-tert-butylphenol	202-679-0	98-54-4	Endocrine disrupting properties (Article 57(f) – environment)

The following remark is to be added to the entry for 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides *(covering any of their individual isomers and combinations thereof)*:

“The combined intrinsic properties justifying the inclusion for the Member State Committee 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:

Persistence, mobility, potential for long-range transport, observed adverse effects (at least the following probable effects for human health: effects on the liver, the

kidney, and the haematological and immune systems and effects on development; at least the following probable effects for the environment: population relevant effects on birds and mammals); as well as low adsorption potential and high water solubility rendering the substance fully bioavailable for uptake via (drinking) water. Together, these elements lead to a very high potential for irreversible effects."

3. Publication

The updated Candidate List shall be published on the Agency's website on 16 July 2019. This decision shall take effect from 16 July 2019.

(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.