

Helsinki, 17 December 2024

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

(Decision of the European Chemicals Agency)

Owner: Mike Rasenberg Activity/Process: 1.5 Identification of SVHC Validity: Indefinite	Distribution: Executive Director Director C HoU C3 ECHAnet
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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 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 30 August 2024, 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 the substances ended on 14 October 2024.
- (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 SVHC was 29 October 2024.
- (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
6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-118-1	2156592-54-8

- (6) 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(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 SVHC for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
O,O,O-triphenyl phosphorothioate	209-909-9	597-82-0
Octamethyltrisiloxane	203-497-4	107-51-7
Perfluamine	206-420-2	338-83-0
Reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives	421-820-9	192268-65-8
Tris(4-nonylphenyl, branched and linear) phosphite	-	-

- (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 22 November 2024, that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHC.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
O,O,O-triphenyl phosphorothioate	209-909-9	597-82-0
Perfluamine	206-420-2	338-83-0
Reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives	421-820-9	192268-65-8
Tris(4-nonylphenyl, branched and linear) phosphite	-	-

- (10) Therefore, these substances are identified as substances of very high concern for the reasons set out in the relevant support documents of the 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 substance tris(4-nonylphenyl, branched and linear) phosphite is already listed on the Candidate List with a condition attached, i.e., "with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)". This entry shall now be updated, pursuant to Article 59(8) of REACH, to reflect that the substance also demonstrates probable serious effects to the environment, due to its endocrine disrupting properties, which are of an equivalent level of concern in accordance with Article 57(f) of REACH independently of the presence of 4-NP in the composition of the substance. Furthermore, it is appropriate to update the section containing further details of the entry to explain that the substance meets these criteria on the basis of its own properties and separately on the basis that it contains $\geq 0.1\%$ 4-NP.
- (12) The Member State Committee at its 88th meeting unanimously agreed that the following substance meets the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Octamethyltrisiloxane	203-497-4	107-51-7

- (13) 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:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-118-1	2156592-54-8	Toxic for reproduction (Article 57c)
O,O,O-triphenyl phosphorothioate	209-909-9	597-82-0	PBT (Article 57d)
Octamethyltrisiloxane	203-497-4	107-51-7	vPvB (Article 57e)
Perfluamine	206-420-2	338-83-0	vPvB (Article 57e)
Reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives	421-820-9	192268-65-8	PBT (Article 57d)
Tris(4-nonylphenyl, branched and linear) phosphite	-	-	Endocrine disrupting properties (Article 57(f) – environment)

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. The entry for tris(4-nonylphenyl, branched and linear) phosphite shall replace the existing entry for tris(4-nonylphenyl, branched and linear) phosphite with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP). The entry shall clarify that the substance meets the criteria for identification as an endocrine disrupter to the environment on the basis of its own properties and separately on the basis that it contains $\geq 0.1\%$ 4 NP.

4. Pursuant to Article 59(10) of REACH the Agency shall on 21 January 2025 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.

5. Entry into effect

This decision shall take effect from 21 January 2025.

(e-signed)

Mike Rasenberg¹
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.