

Helsinki, 16.12.2021

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: 03.02

Identification of SVHC

Validity: Indefinite

Distribution:

Executive Director Deputy Executive Director Director C Quality Manager HoU C3 ECHAnet

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 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 3 September 2021, 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 18 October 2021.
- (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 2 November 2021.
- (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
6,6'-di- <i>tert</i> -butyl-2,2'-methylenedi- <i>p</i> -cresol	204-327-1	119-47-1
tris(2-methoxyethoxy)vinylsilane	213-934-0	1067-53-4

- (6) Therefore, these substances are identified as substances of very high concern for the reasons set out in the relevant Annex XV dossiers 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
(±)-1,7,7-trimethyl-3-[(4-	-	-
methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one		
covering any of the individual isomers and/or		
combinations thereof (4-MBC)		
S-(tricyclo(5.2.1.0 ^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl	401-850-9	255881-94-8
or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-		
ethylhexyl) phosphorodithioate		

- (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 29 November 2021, that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHC:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
(±)-1,7,7-trimethyl-3-[(4-	-	-
methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one		
covering any of the individual isomers and/or		
combinations thereof (4-MBC)		

- (10) Therefore, these substances are identified as substances of very high concern for the reasons set out in the relevant support document 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 76th meeting unanimously agreed that the following substance meets the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
S-(tricyclo(5.2.1.0 ^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl	401-850-9	255881-94-8
or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-		
ethylhexyl) phosphorodithioate		

(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:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
6,6'-di- <i>tert</i> -butyl-2,2'- methylenedi- <i>p</i> -cresol	204-327-1	119-47-1	Toxic for reproduction (Article 57c)
tris(2- methoxyethoxy)vinylsilane	213-934-0	1067-53-4	Toxic for reproduction (Article 57c)
(±)-1,7,7-trimethyl-3-[(4- methylphenyl)methylene]bicyclo [2.2.1]heptan-2-one covering any of the individual isomers and/or combinations thereof (4- MBC)	-	-	Endocrine disrupting properties (Article 57(f) - human health)
S-(tricyclo(5.2.1.0 ^{2,6})deca-3-en- 8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O- (isopropyl or isobutyl or 2- ethylhexyl) phosphorodithioate	401-850-9	255881-94-8	PBT (Article 57d)

- 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 2022 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 2022.

(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. **TEM-0013.09**