

Helsinki, 19 December 2023

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: Mike Rasenberg</p> <p>Activity/Process: 1.3</p> <p>Identification of SVHC</p> <p>Validity: Indefinite</p>	<p>Distribution:</p> <p>Executive Director</p> <p>Director C</p> <p>HoU C3</p> <p>ECHAnet</p>
---	--

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 01 September 2023, 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 16 October 2023.
- (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 31 October 2023.
- (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-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	438-340-0	119344-86-4

- (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/LIST NUMBER	CAS NUMBER
2,4,6-tri-tert-butylphenol	211-989-5	732-26-3
2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol	221-573-5	3147-75-9
Bumetrizole	223-445-4	3896-11-5
Dibutyl phthalate	201-557-4	84-74-2
Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	700-960-7	-

- (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 2023, that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHC.

SUBSTANCE NAME	EC/LIST NUMBER	CAS NUMBER
2,4,6-tri-tert-butylphenol	211-989-5	732-26-3
Dibutyl phthalate	201-557-4	84-74-2
Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	700-960-7	-

- (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.
- (11) As the substance dibutyl phthalate is already listed on the Candidate List, this entry shall now be updated, pursuant to Article 59(8) of REACH, to reflect its additional intrinsic properties of concern.
- (12) Pursuant to Article 59(8) of REACH the Agency shall now include the substances 2,4,6-tri-tert-butylphenol and Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol in the Candidate List for eventual inclusion in Annex XIV to REACH.
- (13) The Member State Committee at its 84th meeting unanimously agreed that the following substances meet the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol	221-573-5	3147-75-9
Bumetrizole	223-445-4	3896-11-5

- (14) 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.

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/LIST NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	438-340-0	119344-86-4	Toxic for reproduction (Article 57c)
2,4,6-tri-tert-butylphenol	211-989-5	732-26-3	Toxic for reproduction (Article 57c); PBT (Article 57d);
Dibutyl phthalate	201-557-4	84-74-2	Endocrine disrupting properties (Article 57(f) – environment);
Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	700-960-7	-	vPvB (Article 57e)
2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol	221-573-5	3147-75-9	vPvB (Article 57e)
Bumetrizole	223-445-4	3896-11-5	vPvB (Article 57e)

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 23 January 2024 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 23 January 2024.

(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.