

Helsinki, 23.06.2021

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</p> <p>Activity/Process: 03.02</p> <p>Identification of SVHC</p> <p>Validity: Indefinite</p>	<p>Distribution:</p> <p>Executive Director</p> <p>Deputy Executive Director</p> <p>Director C</p> <p>Quality Manager</p> <p>HoU C3</p> <p>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 seven 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 and the Agency itself prepared one dossier in the format set out in Annex XV at the request of the European Commission.
- (2) On 09 March 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 23 April 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 10 May 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
2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers	-	-
Orthoboric acid, sodium salt	237-560-2	13840-56-7

- (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
4,4'-(1-methylpropylidene)bisphenol	201-025-1	77-40-7
Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C ₁₄ to C ₁₇]	-	-
Phenol, alkylation products (mainly in para position) with C ₁₂ -rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)	-	-
2,2-bis(bromomethyl)propane 1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA)	221-967-7, 253-057-0, 202-480-9	3296-90-0, 36483-57-5, 1522-92-5, 96-13-9
1,4-dioxane	204-661-8	123-91-1
Glutaral	203-856-5	111-30-8

- (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 03 June 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
4,4'-(1-methylpropylidene)bisphenol	201-025-1	77-40-7
2,2-bis(bromomethyl)propane 1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA)	221-967-7, 253-057-0, 202-480-9	3296-90-0, 36483-57-5, 1522-92-5, 96-13-9
Glutaral	203-856-5	111-30-8

- (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. 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 74th meeting unanimously agreed that the following substances meet the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C ₁₄ to C ₁₇]	-	-
Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)	-	-
1,4-dioxane	204-661-8	123-91-1

- (12) 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 NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers	-	-	Toxic for reproduction (Article 57c)
Orthoboric acid, sodium salt	237-560-2	13840-56-7	Toxic for reproduction (Article 57c)
4,4'-(1-methylpropylidene)bisphenol	201-025-1	77-40-7	Endocrine disrupting properties (Article 57(f) - human health and environment)
2,2-bis(bromomethyl)propane 1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA)	221-967-7, 253-057-0, 202-480-9	3296-90-0, 36483-57-5, 1522-92-5, 96-13-9	Carcinogenic (Article 57a)
Glutaral	203-856-5	111-30-8	Respiratory sensitising properties (Article 57(f) - human health)
Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C ₁₄ to C ₁₇]	-	-	PBT (Article 57d) vPvB (Article 57e)
Phenol, alkylation products (mainly in para position) with C ₁₂ -rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)	-	-	Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - human health and environment)
1,4-dioxane	204-661-8	123-91-1	Carcinogenic (Article 57a) 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 1,4-dioxane:

“The combined intrinsic properties which demonstrate scientific evidence of probable

serious effects to human health and the environment and which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity and yet unknown environmental effects. 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 8 July 2021 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 8 July 2021.

(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.