

Helsinki, 15. 06. 2012

Inclusion of Substances of Very High Concern in the Candidate List

(Decision of the European Chemicals Agency)

<p>Owner: Jukka Malm</p> <p>Validity: Indefinite</p> <p>Classification: Public</p>	<p>Distribution:</p> <p>Director of Regulatory Affairs</p> <p>Quality Manager</p> <p>HoU D.2</p> <p>Executive office</p>
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Whereas

(1) Pursuant to Article 59 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 received from Member States seven Annex XV dossiers for substances which in their opinion meet the criteria of Substances of Very High Concern set out in Article 57 of REACH and the European Chemicals Agency itself prepared six dossiers in the format set out in Annex XV at the request of the European Commission.

(2) The Agency invited all interested parties and Member States to submit comments on the Annex XV dossiers.

(3) The public commenting period for all substances ended on 12 April 2012.

(4) The Agency received no comments on the identification as Substances of Very High Concern for the following substances:

- 1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme),
- 1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME),
- Formamide,
- Lead(II) bis(methanesulfonate),
- 1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (TGIC),
- 1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β -TGIC),
- 4,4'-bis(dimethylamino)benzophenone (Michler's ketone) and
- N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)

Pursuant to Article 59(6) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV.

(5) The Agency received comments on the identification as a Substance of Very High Concern for the following substances:

- Diboron trioxide,
- [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [*with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)*],
- [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Violet 3) [*with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)*],
- 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [*with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)*] and
- α,α -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [*with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)*].

Pursuant to Article 59(7) of REACH these substances were referred to the Member State Committee.

(6) The Member State Committee unanimously agreed via written procedure, which closed on 24 May 2012, and at its 24th meeting (6-8 June 2012) that

- Diboron trioxide,

- [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [*with* $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)],
- [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [*with* $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)],
- 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [*with* $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] and
- α,α -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [*with* $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]

meet criteria set out in Article 57 of REACH for identification as Substances of Very High Concern.

Pursuant to Article 59(8) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV.

THE EUROPEAN CHEMICALS AGENCY

HAS DECIDED THE FOLLOWING:

- 1. Pursuant to Article 59(6) of REACH the following substances shall be included on 18 June 2012 in the Candidate List for eventual inclusion in Annex XIV.**

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	203-977-3	112-49-2	Toxic for reproduction (Article 57 c)
1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	203-794-9	110-71-4	Toxic for reproduction (Article 57 c)
Formamide	200-842-0	75-12-7	Toxic for reproduction (Article 57 c)
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	Toxic for reproduction (Article 57 c)
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	219-514-3	2451-62-9	Mutagenic (Article 57b)
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β -TGIC)	423-400-0	59653-74-6	Mutagenic (Article 57b)
4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	202-027-5	90-94-8	Carcinogenic (Article 57a)
N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	202-959-2	101-61-1	Carcinogenic (Article 57a)

2. Pursuant to Article 59(8) of REACH the following substances shall be included on 18 June 2012 in the Candidate List for eventual inclusion in Annex XIV.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
Diboron trioxide	215-125-8	1303-86-2	Toxic for reproduction (Article 57 c)
[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]-cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Blue 26) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	219-943-6	2580-56-5	Carcinogenic (Article 57a)
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	208-953-6	548-62-9	Carcinogenic (Article 57a)
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	209-218-2	561-41-1	Carcinogenic (Article 57a)
α,α-Bis[4-(dimethylamino)phenyl]-4(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	229-851-8	6786-83-0	Carcinogenic (Article 57a)

3. Publication

The updated Candidate List shall be published on ECHA's website on 18 June 2012.

Done at Helsinki, **15. 06. 2012**



Jukka Malm
Director of Regulatory Affairs¹

¹ Mandated to sign this decision pursuant to the decision of the Executive Director ED/110/2010 delegating the powers to sign decisions to include a substance on the Candidate List for eventual inclusion in Annex XIV under Article 59(6) or Article 59(8) of the REACH Regulation to Jukka Malm, Director of Regulatory Affairs.