

## Authorisation of Substances of Very High Concern

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REACH

**REACH\*** requires from companies an authorisation application for the placing on the market and use of Substances of Very High Concern (SVHC) listed in Annex XIV REACH.

## The authorisation provisions under REACH

1. SVHC ENTER CANDIDATE LIST	Substances are identified as SVHC according to the procedure detailed in Art. 59 and according to the criteria laid down in Art. 57. <b>84 substances</b> have been included in the <a href="#">Candidate List</a> so far. Thirteen SVHC have been added in June 2012!
<b>SVHC included June 2012</b>	<b>Main uses</b>
1,2-bis(2-methoxyethoxy) ethane (Triglyme, TEGDME)	Mainly used as a solvent or as a processing aid in the manufacture and formulation of industrial chemicals. Minor uses in brake fluids and repair of motor vehicles.
1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	Mainly used as a solvent or as a processing aid in the manufacture and formulation of industrial chemicals, including use as an electrolyte solvent in lithium batteries.
Diboron trioxide	Used in a multitude of applications, e.g. in glass and glass fibres, frits, ceramics, flame retardants, catalysts, industrial fluids, metallurgy, nuclear, electrical equipment, adhesives, inks/paints, film developing solutions, detergents and cleaners, reagent chemicals, biocides and insecticides.
Formamide	Intermediate in the manufacture of agrochemicals, pharmaceuticals and industrial chemicals. Minor uses as a solvent, as a laboratory reagent for quality control purposes in forensic laboratories, hospitals, pharmaceutical companies, food and drinks manufacturers and research laboratories. The substance seems to also be used as a plasticiser.
Lead(II) bis(methanesulfonate)	Mainly used in plating processes (both electrolytic and electroless) for electronic components (such as printed circuit boards). The substance seems to also be used for batteries in special applications.
1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (TGIC)	Hardener in resins and coatings, in inks for the printed circuit board industry, electrical insulation material, resin moulding systems, laminated sheeting, silk screen printing coatings, tools, adhesives, lining materials and stabilisers for plastics.
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)	Mainly used as a solder mask ink in the EU. Also used in electrical insulation material, resin moulding systems, laminated sheeting, silk screen printing, coatings, tools, adhesives, lining materials and stabilisers for plastics.
N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	Used as an intermediate in the manufacture of dyes and other substances.
4,4'-bis(dimethylamino) benzophenone (Michler's ketone)	Used as an intermediate in the manufacture of triphenylmethane dyes and other substances. Further potential uses include use as an additive (photosensitiser) in dyes and pigments, in dry film products and as a process chemical in the production of electronic circuit boards.
α,α-Bis[4-(dimethylamino)phenyl]-4-(phenylamino) naphthalene-1-methanol (C.I. Solvent Blue 4) <sup>1</sup>	Mainly used in the formulation of printing and writing inks, for dyeing paper and in mixtures such as windscreen washing agents.
[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) <sup>1</sup>	Used in the formulation of inks, cleaners, and coatings, as well as for dyeing paper, packaging, textiles, plastic products, and other types of articles. It is also used in diagnostic and analytical applications.
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Violet 3) <sup>1</sup>	Used mainly for paper colouring and inks supplied in printer cartridges and ball pens. Further uses include staining of dried plants, use as a marker for increasing the visibility of liquids, staining in microbial and clinical laboratories.
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol <sup>1</sup>	Used in the formulation of writing inks and potentially other inks, as well as for dyeing a variety of materials.

<sup>1</sup> [with ≥ 0.1% of Michler's ketone or Michler's base]

\*REACH: Regulation (EC) 1907/2006 for Registration, Evaluation, Authorisation and restriction of Chemicals, entry into force 1 June 2007

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## Do companies have legal obligations resulting from inclusion of a substance in the Candidate List?

Companies may have legal obligations resulting from the inclusion of substances in the Candidate List which may apply to the listed substances on their own, in mixtures or in articles. More information can be found [here](#).

One of these obligations is to notify ECHA about the presence of SVHC in articles six months after their inclusion in the Candidate List. Key points linked to its duties are explained in our [Special newsletter from April 2011](#).

**Keep informed!** [Public consultations](#) will be launched for new proposed SVHC by ECHA. Intentions of MS to submit an Annex XV dossier as SVHC identification proposal are listed in the [Registry of submitted SVHC intentions](#). You can consult them in order to anticipate a potential impact on your business and for a timely preparation for commenting later in the process if interested.

2. SVHC PRIORITISATION	Based on risk-based criteria and regulatory effectiveness, SVHC are prioritised for Annex XIV REACH inclusion (procedure Art. 58). Consultation on the <a href="#">4th Draft Recommendation</a> for Annex XIV inclusion has been launched. Ten SVHC are proposed to enter the authorisation list of REACH.
4th Draft Recommendation	Main uses
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	intermediate, hardener for epoxy resins, e.g. for the production of rolls, pipes and moulds, and as well for adhesives.
Arsenic Acid	fining agent for ceramic glass (artisanal glass sector), copper foils for printed circuit boards, wood preservatives (outside EU).
Dichromium tris(chromate)	metal surface treatment in the aeronautic/aerospace, steel and aluminium coating, laboratory reagent.
Strontium chromate	coatings, formulations in the aeronautic/ aerospace sector, coil coating sector of steel and aluminium, vehicle coating.
Potassium hydroxyoctaoxodizincatedi-chromate	Coatings in aeronautic/aerospace, steel and aluminium coil coating, vehicle coating.
Pentazinc chromate octahydroxide	vehicle coating and aeronautic/aerospace coating.
Bis(2-methoxyethyl) ether (Diglyme)	reaction solvent, solvent for battery electrolytes, used in sealants, adhesives, fuels, automotive care products, paints.
N,N-Dimethylacetamide (DMAC)	solvent/intermediate in manufacture of various substances and fibres for clothing, industrial coatings, polyimide films, paint strippers and ink removers.
1,2-Dichloroethane (EDC)	Intermediate (e.g. vinyl chloride monomer), solvent in the chemical and pharmaceutical industry.
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	curing agent, cross-linker, chain extender and pre-polymer, used in resins, production of polymer articles, construction and arts.

**Further information Annex XIV Recommendation** at ECHA's website: [Results of Recommendations](#), [ECHA Approach for Prioritisation](#)

**3. ANNEX XIV INCLUSION** **14 substances** have been included meanwhile in Annex XIV REACH ([Regulation \(EU\) 143/2011](#) and its [Corrigendum](#) and [Regulation \(EU\) 125/2012](#)). For details on the substances and their main uses please refer to our thematic [newsletter on Authorisation obligation April 2012](#). **Authorisation applications can be submitted.**

**Support** on Application for Authorisation like [Questions and Answers](#), Templates, Guidance Documents and Downloads from the last events held on Authorisation are available [here](#).

**Pre-submission information sessions:** upon request to ask case-specific questions on your application for authorisation.

**Seminar on applications for authorisation:** 1-2 Oct 2012 at ECHA. This seminar aims to improve the understanding of the authorisation application process, covering topics like the procedural steps, the content requirements for applications, the public consultation on possible alternatives, and the formats, manuals and tools for the application submission. The event focuses on the needs of future applicants but is also open to other stakeholders. Apply until 27 August.

**Workshop on analysing alternatives and socio-economic impacts in authorisation applications:** 2-3 Oct at ECHA. This workshop addresses the practical aspects of how to analyse alternative substances and how to carry out socio-economic analysis when applying for an authorisation for the placing on the market or the use of a substance on the Authorisation List. Apply until 27 August.

<sup>2</sup> based on Annex XV dossiers and information published by ECHA and may provide an incomplete overview. For [further information](#) please refer to the documentation published by ECHA.