

SAFEGUARDS

SGS CONSUMER TESTING SERVICES

HARDLINES, SOFTLINES, ELECTRICAL & ELECTRONIC

NO. 097/09 JUNE 2009

REACH: ECHA RECOMMENDS 7 SUBSTANCES FOR AUTHORISATION

The Member State Committee (MSC) of the European Chemicals Agency (ECHA) recently approved seven substances of very high concern (SVHC) to be included in the Authorisation List (ANNEX XIV). On 1 June 2009 the agency formally submitted to the European Commission its recommendation that these substances should not be used without specific authorisation. The final decision will be taken by the European Commission.

In January 2009, seven (7) substances from the so-called 'Candidate List' of 15 substances of very high concern (SVHC) were proposed to be prioritised for the authorisation process¹. All seven were recently approved by the MSC, a view shared by the ECHA Secretariat². On 2 June, 2009, the ECHA published a press release revealing that they recommend these seven SVHCs should not be used without specific authorisation³. The final decision on the inclusion will be taken by the European Commission under REACH Article 133 comitology procedure.

The adopted list of seven (7) substances of very high concern and examples on their applications are summarised in Table 1. For all 7 substances, the authorisation application and sunset dates recommended by the ECHA have been maintained. The committee agreed with ECHA's draft recommendation with the following exceptions:

- Did not support proposed exemptions for the substances MDA, DEHP, DBP and BBP in artist's paints,



¹[Draft Recommendation of Substances for Inclusion in the List of Substances for Authorisation, Invitation of Comments by Interested Parties, European Chemical Agency, and references therein.](#)

²[First Substances of Very High Concern Move One Step Closer to Tighter Control, News item ECHA/NI/09/07, Helsinki, 26 May 2009, ECHA](#)

³[ECHA Recommends Strict Control for Seven Substances of Very High Concern, Press Release, ECHA/PR/09/07, Helsinki, 2 June 2009](#)



- Was not able to define its opinion on SCCPs in metalworking and for fat liquoring of leather at concentrations $\leq 1\%$. An opinion on this issue needs further legal analysis.

This action by ECHA highlights the need for companies to be aware of the upcoming authorisation requirements and make practical steps to prepare their business for future REACH requirements.

The aim of Authorisation is to ensure that the risks from substances of very high concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable ⁴.

As a result, a manufacturer of chemical substances, importer or downstream user must apply for authorisation for substances included in Annex XIV and ensure the uses of that substance have been authorized.

- on its own or in a preparation,
- or the incorporation of the substance into an article.

Substances being (an integral) part of imported articles cannot be subject to authorisation. However, if an EU-based producer of an article incorporates a substance as such or in preparation into the article, that use of the substance may have to be authorised.

The different steps in the application for authorisation are:

- A chemical safety report covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration),
- An analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives,
- If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how they intend to replace the substance with the alternative,
- An applicant can include a socio-economic analysis in their application, but in cases where it is not possible to demonstrate adequate control of risks and where no suitable alternative exists, one needs to be included in the application.

⁴General Provisions, Article 56, Authorisation, Chapter 1, Title VII, Corrigendum to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 8 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, L 136/3 – L 136/280, Official Journal of the European Union, 29 May 2007.

Item	SVHC	EC No	Substance Category	Possible Applications
1	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	---	<ul style="list-style-type: none"> Flame retardants or plasticiser in textiles and rubber Paints, sealants and adhesives Coolant and lubricant in cutting oils
2	Benzyl butyl Phthalate (BBP)	201-622-7	Phthalate	<ul style="list-style-type: none"> Plasticiser in PVC products (eg toys, flooring) Sealants, adhesives, paints, inks, lacquers, textile and leather coating
3	Bis (2-ethylhexyl) phthalate (DEHP)	204-211-0	Phthalate	<ul style="list-style-type: none"> Plasticiser in polymer products, mainly in PVC PVC used in many different articles - Toys, flooring materials, cables, profiles and roofs, shower curtains, car seats and wallpaper, packaging, sealants, adhesives and inks
4	4,4'-Diaminodiphenyl methane (MDA)	202-974-4	---	<ul style="list-style-type: none"> Hardener for epoxy resins and adhesives Production of high-performance polymers
5	Dibutyl phthalate (DBP)	201-557-4	Phthalate	<ul style="list-style-type: none"> Plasticiser in polymers (mainly PVC) - Coated products, hoses, tubing, wires, cables, packaging Printing inks, adhesives, sealants / grouting agents, nitrocellulose paints
6	Hexabromocyclo dodecane (HBCDD) α -HBCDD β -HBCDD γ -HBCDD	247-148-4 and 221-695-9 (134237-50-6) (134237-51-7) (134237-52-8)	Brominated flame retardant	<ul style="list-style-type: none"> Flame retardant; mainly in polystyrene Production of insulation panels / boards or packaging products Textile applications
7	5- <i>tert</i> -Butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	---	<ul style="list-style-type: none"> Fragrance enhancer Detergents, fabric softeners / conditioners, household cleaning products.

SGS will follow up and inform interested parties as development on REACH and other legislation occur. Throughout our global network of laboratories, we are able to provide a range of services, including analytical testing and REACH consultancy for substances and Safety Data Sheets (SDS) in a comprehensive

of consumer products for the EU and worldwide markets. Please do not hesitate to contact us for further information.

FOR ENQUIRIES:

Global Competences Support Centre: gsc@sgs.com
HingWo Tsang Tel: +852 2774 7420 or Hingwo.Tsang@sgs.com

Asia – Hong Kong. Tel: +852 2334 4481 Fax: +852 2144 7001 mktg.hk@sgs.com
Australasia _ Perth. Tel: +61 (0) 3 9790 3418 Fax: +61 (0) 3 9701 0988 au.cts@sgs.com
Europe – London —UK. Tel: +44(0) 20 8991 3410 Fax: +44 (0) 20 8991 3417 gb.cts.sales@sgs.com
Africa & Middle East – Turkey. Tel: +90 212 225 0024 Fax: +90 212 296 47 82 sgs.turkey@sgs.com
Americas – USA. Tel: +1 973 575 5252 Fax: +1 973 575 1193 Marketing.CTS.US@sgs.com

www.sgs.com Global Competences Support Centre: gsc@sgs.com
If you wish to unsubscribe to this technical bulletin, go here: [Unsubscribe](#)

© 2009 SGS. All rights reserved. This is a publication of SGS, except for 3rd parties' contents submitted or licensed for use by SGS. SGS neither endorses nor disapproves said 3rd parties contents. This publication is intended to provide technical information and shall not be considered an exhaustive treatment of any subject treated. It is strictly educational and does not replace any legal requirements or applicable regulations. It is not intended to constitute consulting or professional advice. The information contained herein is provided "as is" and SGS does not warrant that it will be error-free or will meet any particular criteria of performance or quality. Do not quote or refer any information herein without SGS's prior written consent.

WHEN YOU NEED TO BE SURE

SGS