



**Revised 18th April 2011**

## **Uses covered into the bis-2-Ethylhexyl phthalate registration dossier.**

### Summary :

The REACH DEHP Consortium has prepared a Chemical Safety Report for the registration of bis-2-ethylhexyl phthalate that has been submitted individually by each registrant before November 30<sup>th</sup>. The uses covered by the Exposure scenarios have been described into the CSR following the guidance on information requirements and Chemical Safety Assessment. Chapter R12./ Use Descriptor system. However the Use descriptor System is very generic and a more detailed description is necessary to provide confirmation to an article producer /importer that its use has been covered.

This documents is describing the different uses that the REACH DEHP Consortium considers covered by its exposure scenarios.

# 1. Uses covered into the DEHP CSR

**Table 74. Overview of exposure scenarios for DEHP**

ES n°	ES name	Manufacture	Identified uses					Resulting life cycle stage		Sector of Use (SU)	Preparation Category (PC)	Process Category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	Industrial End use	Consumer use	Professional End use	Service life (for articles)	Waste stage						
ES1	Manufacturing, distribution and use as intermediate	x		x					8, 9	19	1, 2, 3, 4, 8b	NR	1	
ES2	Formulation of DEHP in dry-blends and Platisol formulations		x	x					3,8, 10, 12	32	1, 2, 3, 5, 8b,14	NR	2, 3	
ES3	Polymer processing through compounding, calendering, spread coating, extrusion, injection moulding into articles		x	x		x			3,10,12,22	32	6, 10, 13, 14, 21	NR	5	
ES4	Service life of DEHP contained in articles				x		x	x	21	32	NR	5, 10, 13	10a, 11a	
ES5	Service life of DEHP contained in medical devices				x		x	x	20, 21	32	NR	5, 10	10a, 11a	
ES6	Use as laboratory reagent			x					8, 9, 24	19, 21	15	NR	included in ERC1	

NR: Not relevant

Following this overview, the uses corresponding to articles, are described by the following descriptors combinations:

**General articles**

**SU21,22          PC32          AC 5,10,13          ERC 10a,11a**

**Medical devices articles**

**SU20,21          PC32          AC 5,10,13          ERC 10a,11a**

With these combinations of descriptors , the Lead Registrant is covering the consumers uses of DEHP in plastic, rubber and textile articles outdoor and indoor. Consumers and professional uses of plastic and rubber articles used as medical devices are also covered.

## **2. Notification according to Article 7(2)**

Notification of substances in articles is required of producers and importers of articles when all conditions of Article 7(2) are met:

The substance is included in the candidate list for authorisation.

The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w).

The total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per actor per year.

The substance concentration threshold of 0.1% (w/w) applies to the article as produced or imported. It does not relate to the homogeneous materials or parts of an article, as it may in some other legislation<sup>21</sup>, but relates to the entire article as identified according to chapter 2.

The obligation to notify substances in articles also applies to packaging materials, which may be produced or imported separately as packaging of imported goods. Packaging is to be assessed separately from any object it contains.

A notification is not required for a substance in articles which have been produced or imported before the substance has been included on the candidate list for authorisation. Furthermore, in certain cases an exemption from the obligation to notify applies .

A notification of substances in articles shall be made at the latest 6 months after it has been included on the candidate list of substances for authorisation, but only starting from 1 June 2011. This means that for substances included in the candidate list before 1 December 2010, the notifications have to be submitted not later than 1 June 2011. For substances included in the Candidate List on or after 1 December 2010, the notifications have to be submitted no later than 6 months after the inclusion

### 3.Exemption from registration and notification of substances already registered for a use

According to Article 7(6) a registration or notification of a substance in articles is not required, if the substance has already been registered for that use (i.e. the process by which the substance is included in the articles). This refers to any registration of that use of the substance in the same supply chain or any other supply chain.

On the same basis a producer or importer of articles would be exempted from notification of a substance if he has already registered it for that use himself. In other words, in the particular case that a producer or importer of articles has registration and notification obligations for the same substance in his articles, he would be exempted from the obligation to notify this substance, once he has registered it for that use.

A substance has already been registered for a particular use, if two conditions are fulfilled:

The substance in question is the same as a substance that has already been registered.

The use in question is the same as one of the uses described in a registration of this substance that was already made.

To ensure that the substance in question is the same as a substance that has already been registered, comparing names, and EINECS or CAS numbers of both substances may not always be sufficient. When deciding whether or not two substances can be regarded as the same, the “criteria for checking if substances are the same” given in chapter 5 of the Guidance on substance identification should be applied.

A potential registrant or notifier of a substance in articles would also have to check if the use in question by which the substance is included in his articles is the same as one of the uses described in a registration of this substance that was already made. For this he has to describe the process by which the substance is included in the articles, and into which type of article. This use description should be in line with the use descriptor system explained in chapter R.12 of the Guidance on information requirements and chemical safety assessment. The use descriptor system consists of four elements, specifying the industry sector, the type of mixture, the process and the article category of a substance use. It also specifies whether a substance is foreseen to be intentionally released from an article or not. Please note that (due to the generic architecture of the use descriptor system) using only the elements of the use descriptor system to describe a substance will not be sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) applies. **Therefore, the use in question by which the substance is included in articles has to be described more in detail than just by using elements of the use descriptor system.** To come to a conclusion on whether the substance is considered as registered “for that use” or not, the potential registrant or notifier has to compare the description of his use with those uses already registered for the substance. The conclusion obtained and the considerations that led to it should be well documented in order to be able to demonstrate REACH compliance towards authorities, when required.

#### 4. DETAILED DESCRIPTION OF ARTICLES USES COVERED INTO THE GENERIC CSR PROVIDED BY THE DEHP REACH CONSORTIUM

Processing technique	descriptors	Articles obtained by processing technique	descriptors
Calendering of films/sheets and coated products	SU12,PROC6,PC32,ERC5	Packaging, stationary, curtains, tape, foils Wall coverings	SU21,PC32,AC5,13, ERC10a,11a
Calendering of roofing	SU12,PROC6,PC32,ERC5	Roofing	SU21,PC32,AC13, ERC10a
Extrusion of hoses and profiles	SU12,PROC14,PC32,ERC5	Garden hoses, profiles for electric & electronic equipment	SU21,PC32,AC13, ERC10a,11a
Extrusion of wire and cable	SU12,PROC14,PC32,ERC5	Electric wires and cable	SU21,PC32,AC13, ERC10a,11a
Spread coating of coated fabric	SU12,PROC10,PC32,ERC5	Upholstery, luggage, rainwear, tarpaulins	SU21,PC32,AC5,13, ERC10a,11a
Rotational moulding , dip coating	SU12,PROC13,PC32,ERC5	miscellaneous	SU21,PC32,AC10,13, ERC10a,11a
Extrusion of cable , medical	SU12,PROC14,PC32,ERC5	Cables , medical devices	SU21, 20,PC32, AC10 ,13, ERC11a
Injection moulding	SU12,PROC14,PC32,ERC5	Shoes sole, rubber gaskets	SU21,PC32,AC10 ,13, ERC10a,11a
Low energy manipulation Manual cutting, cold rolling, assembly disassembly	SU12,PROC21,22,PC32,ERC5	All covered articles	SU20,21,PC32,AC5,10 ,13, ERC10a,11a

The DEHP registration dossier is covering the low energy manipulation of plastic articles (AC13) containing up to 50% of DEHP by professional and the consumer use of these plastic articles. Therefore all complex articles resulting from an assembly of primary plastic articles should be considered as covered by the DEHP registration dossier.

We will use the example of electric cables to illustrate this statement:

- 1) Electric cables processing is covered into the Exposure scenario 3 of the DEHP registration
- 2) Low energy manipulation of electric cables containing DEHP is covered into the Exposure scenario 3 of the DEHP registration
- 3) The use of electric cables in the manufacture of complex articles like cars, planes, machinery and mechanical appliance, electrical and electronic articles, electrical batteries and accumulators is covered into the Exposure scenario 3 of the DEHP registration
- 4) The service life of these electric cables included into these complex articles is covered into the Exposure scenario 4 of the DEHP registration

## 5. ARTICLES USES OF DEHP **NOT COVERED** INTO THE GENERIC CSR PROVIDED BY THE DEHP REACH CONSORTIUM

The DEHP REACH consortium have not been found the following uses as common uses . Consequently, these uses have not been covered into the CSR developed by the consortium.

Processing technique	descriptors	Articles obtained by processing technique	descriptors
Calendering of films/sheets and coated products	SU12,PROC6,PC32,ERC5	Food Packaging, Rubber beach toys	SU21,PC32,AC10,13, ERC10a,11a
Calendering of flooring	SU12,PROC6,PC32,ERC5	Flooring,	SU21,PC32,AC13, ERC10a,11a
Spraying of car undercoating	SU12,PROC7,11,PC32,ERC5	Car undercoating	SU21,PC32,AC13, ERC10a,11a
Processing of adhesives and sealants		Adhesives and sealants	
Processing of lacquers/paints		Painted products	
Processing of inks		Printed papers, plastics and textiles	

## 6. ARTICLES USES OF DEHP ALREADY RESTRICTED

As described here below, some uses of DEHP are already restricted and consequently can not be part of the uses covered by the registration dossier

Pursuant to entry 51 of Annex I of Directive 76/769/EEC (and entry 51 of Annex XVII of REACH) DEHP shall not be placed on the market or used as a substance on its own or in a preparation, at concentrations greater than **0.1% by mass** of the plasticised material, in toys and childcare articles.

Since 1 April 2005, cosmetic products containing DEHP shall not be supplied to consumers in the EU, in accordance with Commission Directive 2004/93/EC of 21 September 2004 amending Council Directive 76/768/EEC concerning cosmetic products.

The use of DEHP in food contact materials is already restricted under Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC