

Labelling of medical devices containing phthalates

The revised Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC has included new requirements for medical devices containing certain phthalates. The new requirements are set out in the Directive's Essential Requirements (Annex 1) section 7.5.

Where certain phthalates are an integral part of the medical device material formulation (i.e. not including contaminants or residues), and they are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I of Directive 67/548/EEC, and the device is intended to administer and/or remove medicines, body fluids or other substances to or from the body or devices intended for transport and storage of such body fluids or substances specific labelling is required.

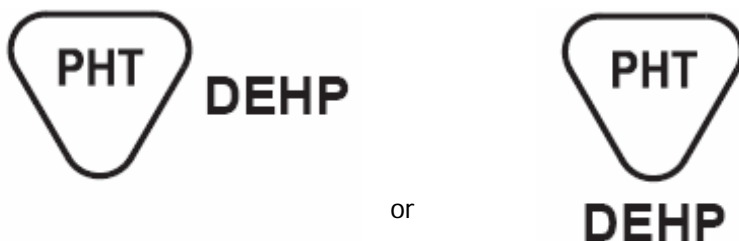
The European Commission has mandated CEN to produce a standard (prEN 15986) that specifies the technical requirements and a suitable specific label. While awaiting the development of this standard and in view of the likely adoption¹ of the symbols described below by means of a harmonized EN standard, Eucomed recommends that the symbols set out below be used.

The symbol and qualifier proposed consists of the generic "contains PHT" symbol accompanied by the name of the phthalate classified as CMR 1 or 2, as a qualifier. The position of the name of this phthalate shall be located adjacent to the generic symbol. These examples are illustrative only and do not represent the only ways in which the requirements of the standard can be met.

Until the relevant EN standard is published and harmonized the symbol would require explanation in the instructions for use.

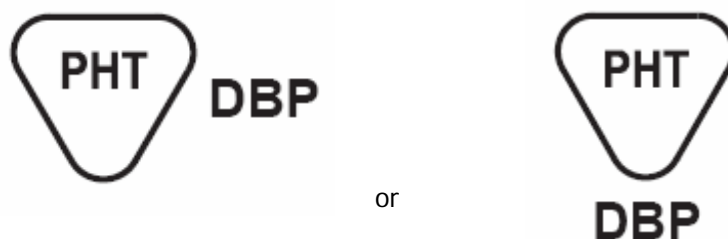
Important note: It is also recommended that the 'negation symbol' should not be used with any of the symbols below.

Symbol for "CONTAINS or PRESENCE of PHTHALATES": Bis(2-ethylhexyl)phthalate (DEHP)



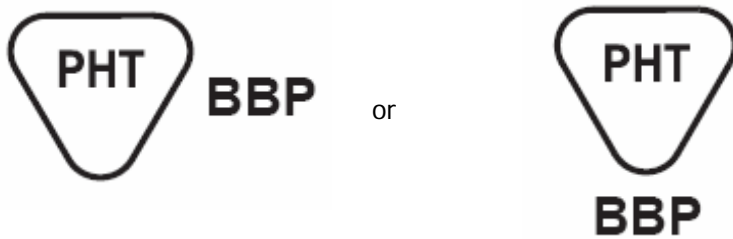
The presence of this symbol indicates that the material used for the manufacture of this specific medical device contains "DEHP"

Symbol for "CONTAINS or PRESENCE of PHTHALATES": Dibutyl phthalate (DBP)



The presence of this symbol indicates that the material used for the manufacture of this specific type of medical device contains "DBP".

Symbol for "CONTAINS or PRESENCE of PHTHALATES": benzyl butyl phthalate (BBP)



The presence of this symbol indicates that the material used for the manufacture of this specific type of medical device contains "BBP"

Symbol for "CONTAINS or PRESENCE of PHTHALATES": Bis(2-ethylhexyl)phthalate (DEHP), Dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP)



The presence of this symbol indicates that the material used for the manufacture of this specific type of medical device, contains several phthalates mentioned with the symbol (DEHP, and/or DBP and/or BBP)

The final standard might be different to what is advised in this document and therefore, Eucomed cannot guarantee the accuracy, adequacy or completeness of any information contained in this document, and cannot be held responsible for any errors or omissions, or for the results obtained from the use thereof.