

Toward DEHP Free Medical Devices

DEHP (**bis(2-ethylhexyl) phthalate (di-2-ethylhexyl phthalate, diethylhexyl phthalate, or dioctyl phthalate)**) is the most common phthalate plasticizer in [medical devices](#) such as intravenous tubing and bags, IV [catheters](#), nasogastric tubes, [dialysis](#) bags and tubing, blood bags and transfusion tubing, and air tubes. DEHP makes these plastics softer and more flexible and was first introduced in the 1940s in blood bags. For this reason, concern has been expressed about leachates of DEHP transported into the patient, especially for those requiring extensive infusions or those who are at the highest risk of developmental abnormalities, e.g. [newborns](#) in [intensive care nursery](#) settings, [hemophiliacs](#), [kidney dialysis](#) patients, neonates, premature babies, lactating, and pregnant women. According to the European Commission [Scientific Committee on Health and Environmental Risks](#) (SCHER), exposure to DEHP may exceed the tolerable daily intake in some specific population groups, namely people exposed through medical procedures such as kidney dialysis.^[10]

USA

The [American Academy of Pediatrics](#) has advocated not to use medical devices that can leach DEHP into patients and, instead, to resort to DEHP-free alternatives.^[11] In July 2002, the U.S. FDA issued a Public Health Notification on DEHP, stating in part, "We recommend considering such alternatives when these high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males" noting that the alternatives were to look for non-DEHP exposure solutions;^[12] they mention a database of alternatives.^[13] The [CBC](#) documentary *The Disappearing Male* raised concerns about [sexual development](#) in male fetal development, [miscarriage](#)), and as a cause of dramatically lower [sperm counts](#) in men.^[14] A review article in 2010 in the *Journal of Transfusion Medicine* showed a consensus that the benefits of a lifesaving treatments with these devices far outweigh the risks of DEHP leaching out of these devices. Although more research is needed to develop alternatives to DEHP that gives the same benefits of being soft and flexible which are required for most medical procedures. If a procedure requires one of these devices and if patient is at high risk to suffer from DEHP then a DEHP alternative should be considered if medically safe.^[15]

European Union

Concerns about chemicals ingested by children when chewing plastic toys prompted the [European Commission](#) to order a temporary ban on phthalates in 1999, the decision of which is based on an opinion by the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). A proposal to make the ban permanent was tabled. Until 2004, EU banned the use of DEHP along with several other phthalates ([DBP](#), [BBP](#), [DINP](#), [DIDP](#) and [DNOP](#)) in toys for young children.^[33] In 2005, the Council and the Parliament compromised to propose a ban on three types of phthalates ([DINP](#), [DIDP](#), and [DNOP](#)) "in toys and childcare articles which can be placed in the mouth by children". Therefore, more products than initially planned will thus be affected by the directive.^[34] In 2008, six substances were considered to be of very high concern ([SVHCs](#)) and added to the Candidate List including [musk xylene](#), MDA, [HBCDD](#), DEHP, [BBP](#), and [DBP](#). In 2011, those six substances have been listed for Authorization in Annex XIV of [REACH](#) by Regulation (EU) No 143/2011.^[35] According to the regulation, phthalates including DEHP, BBP and DBP will be banned from February 2015.^[36]

In 2012, Danish Environment Minister [Ida Auken](#) announced the ban of DEHP, DBP, DIBP and BBP, pushing [Denmark](#) ahead of the European Union which has already started a process of phasing out phthalates.^[37] However, it was postponed by two years and would take effect in 2015 and not in December 2013, which was the initial plan. The reason is that the four phthalates are far more common

than expected and that producers cannot phase out phthalates as fast as the Ministry of Environment requested.^[38]

In 2012, [France](#) became the first country in the EU to ban the use of DEHP in pediatrics, neonatal, and maternity wards in hospitals.^[39]

DEHP has now been classified as a Category 1B reprotoxin,^[40] and is now on the Annex XIV of the European Union's [REACH](#) legislation. DEHP has been phased out in Europe under REACH and can only be used in specific cases if an authorization has been granted. Authorizations are granted by the European Commission, after obtaining the opinion of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency (ECHA).

California

DEHP is classified as a "chemical known to the State of California to cause cancer and birth defects or other reproductive harm" (in this case, *both*) under the terms of [Proposition 65](#).^[41]

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