

Annex 2 Substitution of hazardous substances

Products must meet all chemicals of concern criteria:

1. LATEX – Does not contain intentionally added latex in any material touched by patients or practitioners.ⁱ
2. EUROPEAN UNION CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN FOR AUTHORIZATION – All homogenous materials contain less than 1000 ppm of intentionally added SVHCs.ⁱⁱ

**The Candidate List can be found at <https://echa.europa.eu/candidate-list-table>.*

3. BISPHEENOL A (BPA) – all homogeneous materials contain less than 1000 ppm of intentionally added Bisphenol A and related structural/functional analogues*.ⁱⁱⁱ

**Structural/functional analogues include: bisphenol AP, bisphenol AF, bisphenol B (BPB), bisphenol C, bisphenol C2, bisphenol E (BPE), bisphenol F (BPF), bisphenol G, bisphenol M, bisphenol S (BPS), bisphenol P, bisphenol PH, bisphenol TMC, bisphenol Z, and 4-cumylphenol (HPP) or Bisphenol A derived chemicals.*

4. POLYVINYL CHLORIDE (PVC) – Does not contain Polyvinyl Chloride.^{iv}
5. PHTHALATES – All homogenous materials contain less than 1000 ppm of phthalates*.^v

**Phthalates include Di-2-ethyl hexyl phthalate (DEHP) CAS 117-81-7, 1,2-Benzenedicarboxylic acid CAS 68515-42-4, Benzylbutylphthalate (BBP) CAS 85-68-7, di-C6-8-branched alkyl esters, C7-rich CAS 71888-89-6, Dibutyl phthalate (DBP) CAS 84-74-2, 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters CAS 68515-51-5 and CAS 68648-93-1, Dihexyl phthalate (DHP) CAS 84-75-3, Diisobutyl phthalate (DIBP) CAS 84-69-5, Di-isodecyl phthalate (DIDP) CAS 68515-49-1 or 26761-40-0, Diisononyl phthalate (DINP) CAS 28553-12-0 or 68515-48-0, Dioctyl phthalate (DNOP) CAS 117-84-0, Dipentylphthalat (DDP) CAS 131-18-0, Tris(2-chloroethyl) phosphate (TCEP) CAS 115-96-8 and Dicyclohexyl phthalate (DCHP) CAS 84-61-7 (above 1000ppm). All listed phthalates, except those marked red, are identified as SVHCs and included on the Candidate List.*

6. ANTIMICROBIAL / ANTIBACTERIAL AGENTS – Does not contain intentionally added antimicrobial/antibacterial agents.^{vi}

ⁱ Latex presents a problem for patients and staff with allergic reactions.

ⁱⁱ The Candidate List and the national [list of priority substances](#) are both drivers for substitution. We will update Annex 2 accordingly if relevant substances are added to the priority list and not (yet) identified as a SVHC. The priority list is updated annually.

ⁱⁱⁱ The concern covers the life cycle of Bisphenol and therefore this requirement covers the whole supply chain, including its presence in any phase of manufacturing. Bisphenol A can adversely affect reproduction.

^{iv} The manufacture and disposal of this material releases dioxins, a known carcinogen, into the environment.

^v Following the precautionary principle, substances are included if they are suspected of being harmful to humans or the environment. A blanket requirement of 'phthalate free' in tenders is difficult to follow-up in the contract period, since control tests on products are done on specific substances.

^{vi} Antibacterial/antimicrobial agents: Widespread use of antibiotics and antimicrobials in livestock as well as products has perpetuated antibiotic resistance. Antibacterial and antimicrobial agents include, but are not limited to, silver and triclosan. Exemptions to the requirements are given where the substance is added for medical use, for example in antibacterial sutures or in wound dressings.