



European healthcare's phase-out list for chemicals of concern

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The European healthcare sector seeks to phase out chemicals of concern from supply chains and medical products and accelerate the phase-out of the highest priority chemicals of concern.

The healthcare sector will continue working with suppliers to achieve this goal. Exemptions to the criteria will be made when safer alternatives do not exist and when specially requested in tenders for essential use.

Chemicals of concern criteria:

Note limit values where indicated.

- 1. Candidate list of substances of very high concern (SVHCS)** – All articles or component articles of a complex article do not contain substances listed on the [Candidate List](#)ⁱ of the EU chemicals regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals EC 1907/2006) over 0.1% weight by weight (w/w).
- 2. Carcinogenic, mutagenic or substances toxic to reproduction (CMR substances of category 1A or 1B)** – All articles in accordance with Article 52 and 10.4.1 of Annex I of the [Medical Device Regulation](#) (MDR)ⁱⁱ do not contain substances which are CMR of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP) over 0.1% (w/w).
- 3. Polyvinyl chloride (PVC)** – All articles or component articles of a complex article do not contain PVC.
- 4. Phthalates** – All articles or component articles of a complex article do not contain Phthalates listed on the Candidate List or [Restriction List](#)ⁱⁱⁱ of the REACH Regulation, nor on the [ChemSec SIN List](#)^{iv} over 0.1% (w/w).

ⁱ Candidate List: echa.europa.eu/da/candidate-list-table

ⁱⁱ The MDR: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
Endocrine-disrupting substances in the MDR are covered by the Candidate List and the restricted Phthalates.

ⁱⁱⁱ Restriction List: echa.europa.eu/da/substances-restricted-under-reach

^{iv} ChemSec SIN List: sinlist.chemsec.org