



BOMCHECK Version 8.4
Guidance Webinar

Agenda

3 new (SVHC) REACH Candidate List substances

POPs Stockholm Convention list additions and amendments

Other Restricted or Declarable Substances

Substances of Concern

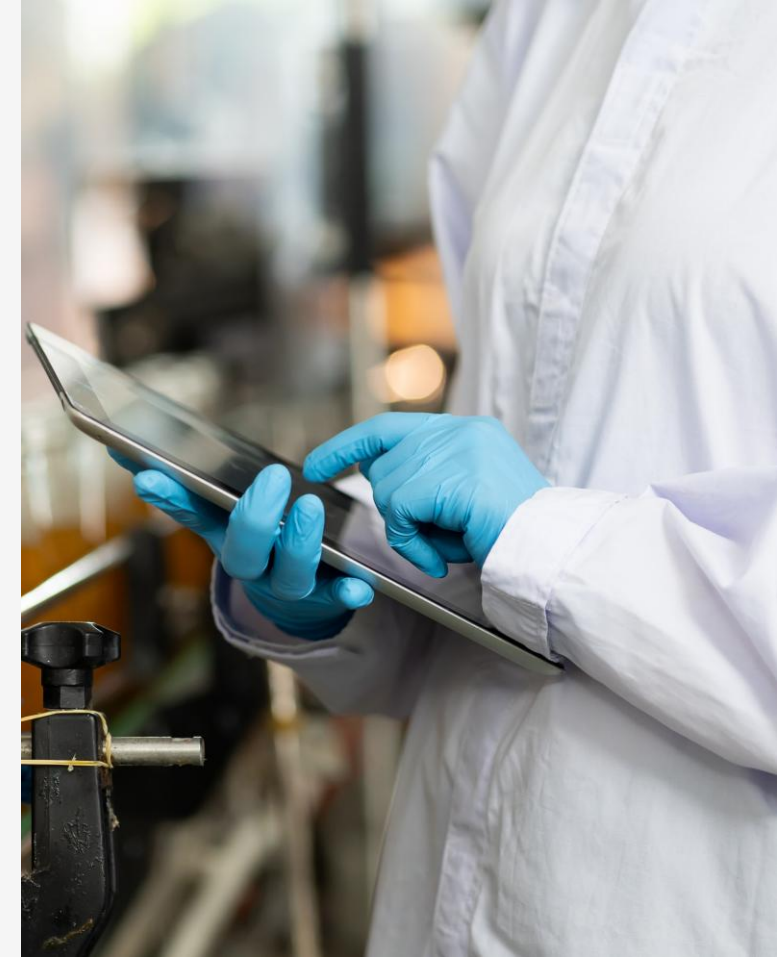
EU MDR (CMR 1A & 1B and endocrine disrupting) substances

Technical Demonstration

3 New (SVHC) REACH Candidate List substances

Declaration Required

- 3 new SVHCs added to REACH Candidate List on 25 June 2025
- You should update your RCDs for these new SVHCs to state whether they are included $>0.1\%$ w/w at the article level within your parts
- If you have the additional SCIP module, BOMcheck will automatically generate updated SCIP dossiers and submit them to the SCIP database for any affected parts



3 new (SVHC) REACH Candidate List substances

Substance name	CAS#	Action required?
1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane	17928-28-8	Yes - This substance is a linear siloxane-based compound commonly used as a processing aid, intermediate, or additive in various applications. It is particularly used in surface treatments and coatings where it serves as a functional additive. However, its volatility may lead to evaporation, meaning it may not remain in some finished applications.
Decamethyltetrasiloxane (L4)	141-62-8	Yes - Decamethyltetrasiloxane is a linear siloxane widely used in silicone polymer manufacturing, cosmetics, lubricants, and electronics. As an intermediate and mould release agent it is unlikely to be present above trace amounts in supplied articles. However, uses as an industrial lubricant and grease, surface treatment and heat transfer fluid may result in presence >0.1% w/w.
Reactive Brown 51	No CAS number(s) provided.	No - Reactive Brown 51 is a complex azo reactive dye with good water solubility and adhesion properties. It is primarily used in textile treatment products and textile dyeing and is not present >0.1% in supplied articles.

POPs Stockholm Convention list additions

Two new entries have been added to the POPs Stockholm Convention List in BOMcheck

Chlorinated Paraffins with carbon chain lengths in the range of C14-17 and Chlorination Levels \geq 45% Chlorine by Weight (MCCPs)

- MCCPs can be used as plasticisers, flame retardants and leather treatment agents in the production of plastics, rubber, textiles, synthetic leather, sealants and adhesives. May also be used in paints and coatings to provide flame retardant and waterproof coatings.

Long-chain Perfluorocarboxylic Acids (LC-PFCAs), their salts, and related compounds

- LC-PFCAs may be used due to their waterproof, oil-proof, and high-temperature resistant properties. This includes applications such as a plasticisers, flame retardants, lubricants, adhesives, sealants, metalworking fluids, paints and coatings, and leather, etc.

Declaration Required:

- You must confirm if these substances are intentionally used in your parts or materials
- Added to the POP's list in the RCD tool with a maximum concentration of "No intentionally added content"

POPs Stockholm Convention list amendments

Amendments to existing entries

PFOS and its salts: 0.025 mg/kg (25 ppb) UTC limit

PFOS-related compounds: 1 mg/kg (1 ppm) UTC limit for individual or sum

Polychlorinated biphenyls (PCBs): 0.2 mg/kg (0.2 ppm) UTC limit for the sum of PCBs in substances, mixtures and articles

Polybrominated diphenyl ethers (PBDEs): 10 mg/kg (10 ppm) UTC limit for the sum of PBDEs in mixtures and articles

UV-328: 1 mg/kg (1 ppm) UTC limit

Pentachlorophenol (PCP) its salts and esters: 5 mg/kg (5 ppm) UTC limit

A UTC (Unintentional Trace Contaminant) is a small, unintended amount of a restricted or banned substance that is present in a product as an impurity, within regulated safety limits


Understand the Thresholds

- Any threshold above “no intentionally added content” for a POPs substance (e.g., 0.0001% or 1 ppm), refers to the Unintentional Trace Contaminant (UTC) limit
 - This means the substance is not intentionally used;
 - However, trace amounts up to the specified limit (e.g., 1 ppm) may be tolerated only if they are unintentional

Other Restricted or Declarable Substances

Amendment to **Bisphenol A** in Food Contact Materials

On December 31, 2024, the EU issued Commission Regulation (EU) 2024/3190 on the use of BPA (CAS 80-05-7) and other bisphenols and bisphenol derivatives with harmonized classification for specific hazardous properties in certain Food Contact Materials and articles.

Parts which come into contact with food		Set Group		
Bisphenol A (BPA) and hazardous bisphenols or hazardous bisphenol derivatives BPA, BPS, BPAF, TBBPA	 No content permitted in products which contact with food.	Yes	No	Missing

Declaration Required

- Declaration required for this entry in the Other Restricted or Declarable Substances, with threshold set as “No content permitted in products which contact with food”

Industry Restricted and Declarable Substances

Substances of Concern

A new entry has been added to the Industry Restricted and Declarable Substances list.

Substances of Concern, which are subject to disclosure requirements under the ESRS (specifically E2-5) and support for the EU Taxonomy, Do No Significant Harm (DNSH)

A list of 3,531 individual substances with CAS numbers meeting these criteria are included within the new entry.

Declaration Required

- Indicate compliance = No and if you know the substance CAS number or name use the substance search box to select the correct substance
- CAS Checker – You can use the CAS check option to upload a formatted CAS number list to check for any matching CAS numbers

The screenshot displays the Sphera BOMcheck software interface. The main window shows the 'Industry Restricted and Declarable' section, which includes a table of substances. A blue box highlights the 'Substances of Concern' entry, and a blue arrow points to it. A modal window titled 'Additional Data Capture' is open on the right, showing a list of 4 selected substances with their CAS numbers and names.

Substances	Maximum Concentration	Does the part contain
Beryllium and Beryllium Compounds	0.1% by weight (1 000 ppm) of any material	
Substances of Concern	No intentionally added content	
Precious Metals and Rare Earth Minerals		
Rare earth minerals	No intentionally added content	
Precious metals	No intentionally added content	
Brominated Flame Retardants - (BFRs) declarable		

Additional Data Capture
Substances of Concern

Please add details of the Substances of Concern which can be found in your parts. You may use the search function below or upload a formatted CAS number list to automate the allocation of substances from this list. (Please note, BOMcheck will run this assessment in your browser and will not store your CAS number list.)

[Run CAS Check \(TXT, CSV, XLSX\)](#) [Substances of Concern reference list](#)

You have selected 4 options.

Substances Details 4 Selected substances

- 335-67-1 Al3-19341
- 1763-23-1 1-Octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,8,8,8-heptafluoro-
- 355-46-4 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-
- 375-95-1 Nonanoic acid, heptafluoro-

[Save](#)

EU MDR (CMR 1A & 1B and endocrine disrupting) substances



The CMR 1A & 1B substances list in the RCD tool will be updated to include additional substances and new SVHC's

Declaration required

- Action is only required for parts used in medical devices
- The entry for CMR 1A & 1B substances in the RCD tool has been set to missing for all relevant suppliers based on the scope question “Does the part have invasive contact with, or transport fluids or gases which contact the patient?”
- Suppliers will have to re-enter their compliance status as “Yes” or “No” to the updated list
- The updated list can be found in the entry info sheet in the RCD tool

CMR 1A and 1B
substances and
endocrine disrupting
substances



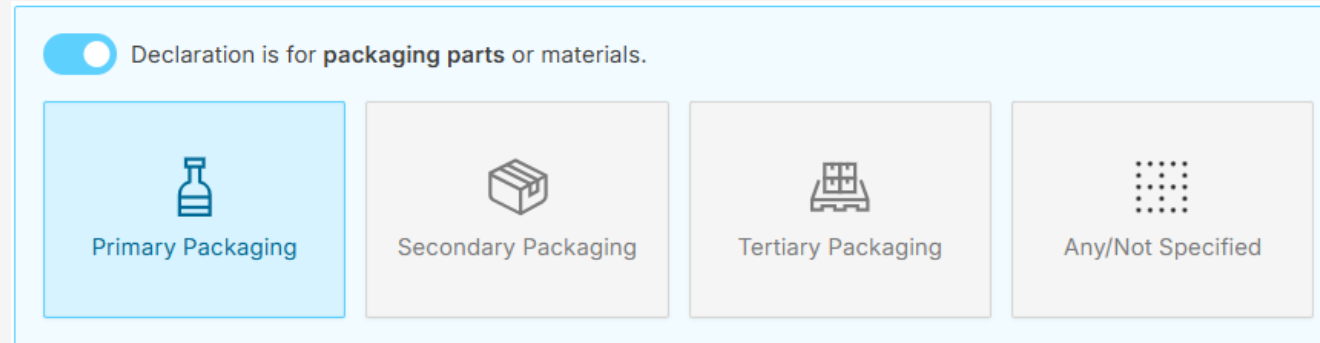
0.1% by weight (1 000ppm) in any
material which has invasive contact
with the patient, or any material which
transports or stores fluids or gases
which contact the patient

Yes

No

Missing

Packaging Declaration Tool Update



The screenshot shows a user interface for the Packaging Declaration Tool. At the top, there is a toggle switch that is turned on, with the text "Declaration is for packaging parts or materials." next to it. Below this, there are four rectangular boxes for selection. The first box, labeled "Primary Packaging", is highlighted in light blue and contains an icon of a bottle. The other three boxes, "Secondary Packaging" (with a box icon), "Tertiary Packaging" (with a pallet icon), and "Any/Not Specified" (with a grid icon), are in a light gray color.

- **Unified Toolset:** Declare packaging part and material compliance through the new RCD Tool
- **Full Packaging Scope:** Make declarations for all packaging levels – primary (sales), secondary (grouped) and tertiary (transport).
- **Expanded Regulatory Coverage:** Access BOMcheck's reassessed and extended DSLs, now including packaging-specific legislation.
- **Circularity Data Capture:** Include Extended Producer Responsibility (EPR) and other circularity data in packaging declarations.
- **Future-Proof Compliance:** Prepare for upcoming legislation, such as PFAS restrictions on packaging.
- **Search & Export Packaging:** Retrieve and export packaging declarations in standard IPC formats for integration with other systems.

Sphera Customer Network

BOMcheck provides tiered ticketing support, for product and regulatory support queries through the Sphera Customer Network.

For any technical enquiries or questions, you can register and submit your ticket there.

Benefits

- 24/7 Tier 1 Support
- Submit & Manage Tickets
- Influence Product development with Enhancement Requests

Guidance to register can be found here: [Sphera Customer Network](#)

Visit the  **sphera** Customer Network (SCN)

How to raise a Packaging Declaration in the RCD tool

How to update an individual Regulatory Compliance Declaration (RCD)