

sphera

BOMcheck v8.4

Quick Reference Guide

Summary Table

Substance name	Category	Action required?
1,1,1,3,5,5,5-heptamethyl-3- [(trimethylsilyl)oxy]trisiloxane	REACH Candidate List (SVHC)	Yes - Used in surface treatments and coatings
decamethyltetrasiloxane	REACH Candidate List (SVHC)	● Yes – Used in lubricants and greases, surface treatments and heat transfer fluid
Reactive Brown 51	REACH Candidate List (SVHC)	No – Reactive dye used in textiles and not present > 0.1% in supplied articles
Bisphenol S	California Proposition 65	No – Previously added to BOMcheck as part of version 7.0 in February 2023
Vinyl Acetate	California Proposition 65	No – Reacted during the manufacturing process and not expected to be present in final products after polymerisation
Bisphenol A (BPA) and hazardous bisphenols or hazardous bisphenol derivatives	Other Restricted or Declarable Substances (parts which contact food)	Yes (partial) - Applicable to parts which come into contact with food. Amendment to existing entry to add other Bisphenols



Summary Table

Substance name	Category	Action required?
Substances of Concern	Industry Restricted and Declarable Substances	● Yes – Substances of Concern are subject to disclosure requirements under ESRS E2-5. See entry in RCD tool for further information
EU MDR – CMR 1A & 1B and endocrine disrupting substances	Other Restricted or Declarable Substances (medical devices)	Yes (partial) - Applies only to medical device parts/equipment. List updated with substances from the Candidate List
Chlorinated Paraffins with carbon chain lengths in the range of C14-17 and Chlorination Levels ≥ 45% Chlorine by Weight (MCCPs)	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – This entry has been added to BOMcheck as the substance is due to be listed for elimination under Annex A of the POPs Stockholm Convention
Long-chain Perfluorocarboxylic Acids (LC-PFCAs), their salts, and related compounds	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – This entry has been added to BOMcheck as the substance is due to be listed for elimination under Annex A of the POPs Stockholm Convention
PFOS and its salts	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – To align with an EU POPs amendment this entry in BOMcheck has been updated to add a limit for Unintentional Trace Contaminants



Summary Table

Substance name	Category	Action required?
PFOS-related compounds	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – To align with an EU POPs amendment this entry in BOMcheck has been updated to add a limit for Unintentional Trace Contaminants
Polychlorinated biphenyls (PCBs)	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – To align with an EU POPs amendment this entry in BOMcheck has been updated to add a limit for Unintentional Trace Contaminants
Polybrominated diphenyl ethers (PBDEs)	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – To align with an EU POPs amendment this entry in BOMcheck has been updated to add a limit for Unintentional Trace Contaminants
<u>UV-328</u>	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – To align with an EU POPs amendment this entry in BOMcheck has been updated to add a limit for Unintentional Trace Contaminants
Pentachlorophenol (PCP) its salts and esters	Persistent Organic Pollutants (POPs) Stockholm Convention	● Yes – To align with an EU POPs amendment this entry in BOMcheck has been updated to add a limit for Unintentional Trace Contaminants



1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (M3T)

CAS: 17928-28-8

Declaration required

- SVHC
- Can be found in supplied articles
 >0.1% w/w



- This substance is a linear siloxane-based compound commonly used as a processing aid, intermediate, or additive in various applications
- Substance may be present >0.1% w/w in supplied articles, particularly 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.
- Its functions range from improving spreadability and durability in coatings to acting as a conditioning agent in personal care formulations.



Decamethyltetrasiloxane (L4)

CAS: 141-62-8

Declaration required

- SVHC
- Can be found in supplied articles >0.1% w/w



- Decamethyltetrasiloxane is a linear siloxane widely used in silicone polymer manufacturing, cosmetics, lubricants, and electronics
- It's low surface tension and high fluidity make it effective in friction reduction and anti-stick applications, particularly under high temperatures.
- 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.







Bisphenol A (BPA) and hazardous bisphenols or hazardous bisphenol derivatives

Other Restricted or Declarable Substances

Declaration required

- Entry on the Other Restricted or Declarable Substances list
- Applicable only to food contact materials
- Re-declaration required for this entry due to the new substances

Amendment to existing entry

 Related bisphenols added to the existing entry in BOMcheck



Substance Name	CAS Number	Classification
Bisphenol A (BPA)	80-05-7	Repr. 1B (May damage fertility)
Bisphenol AF (BPAF)	1478-61-1	Repr. 1B (Suspected of damaging fertility)
TBBPA: 4,4'-(isopropylidene)bis(2,6-dibromophenol)	79-94-7	Carc. 1B (May cause cancer)
Bisphenol S	80-09-1	Repr. 1B
4,4-isobutylethylidenediphenol	6807-17-6	Repr. 1B



Substances of Concern

Industry Restricted and Declarable Substances

Declaration required

- New entry on the Industry Restricted and Declarable Substances list
- Substances of concern are subject to disclosure requirements under the EU ESRS, specifically ESRS E2-5
- The full list of substances for this entry is available in the RCD infosheet



How to declare Substances of Concern in BOMcheck

Individual substance declaration - If you know the name or CAS number for the specific substance present in your part(s), you should indicate this in the RCD tool by selecting compliance = No and then using the substance search box to select the correct substance.

CAS Checker – You can use the CAS Check option for this entry in the RCD tool to 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).

Any matching CAS numbers that appear in your part(s) will be displayed. Any non-matching CAS numbers will not be saved.



How to declare POPs substances in BOMcheck?

- Follow the "No Intentionally Added Content" Rule
 - You must confirm for all POPs substances, if they are intentionally added to your product or materials
- 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

Example

- If the POPs entry lists a threshold of 0.0001% (1 ppm) for a substance:
 - You must declare that the substance is not intentionally added
 - You can still indicate compliance= yes, if trace levels are ≤ 1 ppm and are unintentional



New entry

- Chlorinated Paraffins with carbon chain lengths in the range of C14-17 and Chlorination Levels ≥ 45% Chlorine by Weight
- Also known as MCCPs



Declaration required

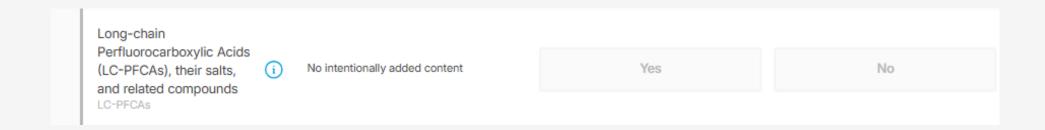
- You must indicate if this substance is intentionally added to your parts or materials
- This entry contains the same group substances as the MCCPs entry in the REACH Candidate List

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



New entry

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



Declaration required

- You must indicate if this substance is intentionally added to your parts or materials
- The RCD infosheet contains information on the substances included in this group

- LC-PFCAs may be used due to their waterproof, oilproof, and high-temperature resistant properties
- This includes applications such as a plasticizer, flame retardant, lubricant, adhesive, sealant, metalworking fluid, paint and coating, and leather, etc.
- They are widely used in textiles, food packaging, electronic equipment and firefighting foam



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

Declaration required

- You should indicate (compliance = yes or no) if any of the substances are intentionally added to your parts or materials
- Unintentional trace contaminants are allowed up to the levels indicated for each individual entry
- Typical applications for each entry is available in the infosheet guidance in the RCD tool



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

Declaration required

Who is affected?

• Action is only required for parts used in medical devices and where the part has invasive contact with the patient

What's changed?

- The CMR 1A & 1B substances list in the RCD tool has been updated to include additional substances from the Candidate List
- The entry for CMR 1A & 1B substances in the RCD tool will be set to "missing information" for all applicable suppliers

What suppliers need to do?

- Suppliers must indicate compliance "Yes" or "No"
- The full list and screening of CMR 1A and 1B substances is available here





