



BOMCHECK Version 8.3
Guidance Webinar

Agenda

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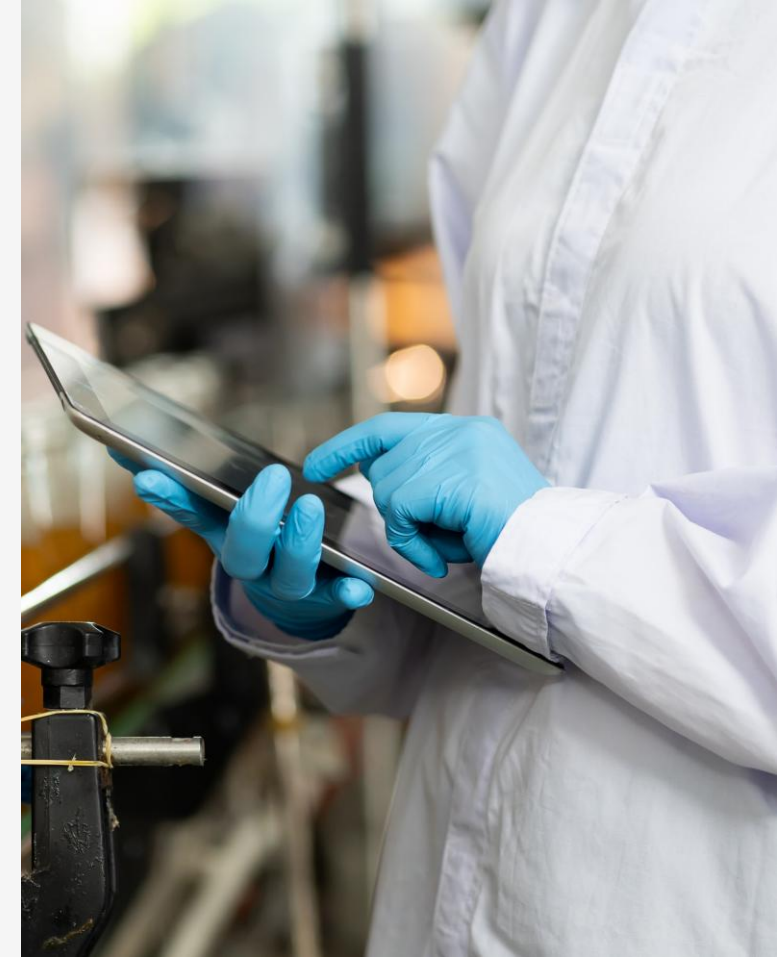
EU MDR (CMR 1A & 1B and endocrine disrupting) substances

How to update your Regulatory Compliance Declaration

6 New (SVHC) REACH Candidate List substances

Declaration Required

- 1 new SVHC added to the REACH Candidate List on 7th November 2024
- 5 new SVHC added to REACH Candidate List on 21st January 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



6 new (SVHC) REACH Candidate List substances

| Substance name | CAS# | Action required? |
|--|--------------|---|
| Triphenyl phosphate | 115-86-6 | Yes. Triphenyl phosphate (TPhP) is widely used as a flame retardant and plasticizer across industries such as electronics, textiles, furniture, paints and coatings. Its usage has increased following the phase-out of PBDEs. Concentrations can vary but may reach 20-30% w/w depending on the application. |
| 6-[(C10-C13)-alkyl- (branched, unsaturated)- 2,5-dioxopyrrolidin-1- yl]hexanoic acid | 2156592-54-8 | Yes. Used in hydraulic fluids, lubricants, greases, metalworking fluids, and as a surfactant in personal care products. |
| O,O,O-triphenyl phosphorothioate | 597-82-0 | Yes. Functions as a lubricant additive, flame retardant, plasticizer, and precursor for organophosphorus insecticides and herbicides. Its sodium salt form is used as an antiseptic and disinfectant |

6 new (SVHC) REACH Candidate List substances

| Substance name | CAS# | Action required? |
|---|-------------|--|
| Octamethyltrisiloxane | 107-51-7 | Yes. Octamethyltrisiloxane is a highly volatile substance commonly used in personal care products, industrial lubricants, coatings, defoamers, adhesives, and electronic components. It's volatility often leads to evaporation meaning it may not remain in some finished applications. |
| Perfluamine | 338-83-0 | Yes. Perfluamine is a fluorinated compound valued for it's chemical stability. It's used in heat transfer fluids, oxygen transport systems, lubricants, inert solvents, and optical devices. |
| Reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives | 192268-65-8 | Yes. A mixture used in various industrial applications. It shares similar applications to TPPT including lubricants, flame retardants, and plasticisers |

REACH Restriction (Annex XVII) addition

The European Union (EU) has issued legislation to regulate undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances under entry 79 in Annex XVII to Regulation (EC) No 1907/2006. The restrictions will be implemented in phases, starting 10 April 2026.

The restriction only applies to certain applications which include textiles, leather, furs, hides and food contact materials. The restrictions will be implemented in phases.

Implementation Dates

10 April 2026: Firefighting foams (training/testing)

10 October 2026: Textiles, leather, footwear, paper, cosmetics

10 October 2027: Additional textiles, leather, furs, hides

10 October 2029: Firefighting foams (civil aviation)

Declaration Required

Two new entries will be added to the REACH Restrictions list in BOMcheck:

- **sum of undecafluorohexanoic acid (PFHxA) and its salts** with a threshold of 0.0000025% by weight (25ppb) of any material used in restricted applications
- **sum of PFHxA-related substances** with a threshold of 0.0001% (1000 ppb) of any material used in restricted applications



TSCA 6(h) addition

- As part of section 6(h) of the Toxic Substances Control Act in October 2024 the EPA issued a final rule for DecaBDE
- The EPA has prohibited the manufacture, processing and distribution of DecaBDE and products containing DecaBDE.

Uses/Applications

- DecaBDE is a flame retarded in various applications such as wire and cable insulation, adhesives, coatings, and textile coatings

Declaration Required:

- A new entry has been added to the Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h) TSCA list in BOMcheck which was previously accounted for in the EU RoHS list:
- **Decabromdiphenylether (DecaBDE)** with a concentration of “No intentionally added content”


POPs Stockholm Convention list additions and amendments

One New entry has been added to the EU POP's list to ensure BOMcheck aligns with IEC 62474 standard.

- **PFOA-related substances** with a threshold in BOMcheck of 0.0001% or 1 ppm of the article

One update has been made to an existing substance to align with the Japan Chemical Substance Control Law.

- The threshold for **Polybrominated Diphenyl Ethers (PBDEs)** has been amended from 0.05% w/w to “No intentionally added content”.
- An exemption is available in the EU for this substance for parts used exclusively in electrical or electronic equipment.

| | | | | | |
|---|--|-----|----|--|---------|
| Polybrominated diphenyl ethers (PBDEs) PBDEs |  No intentionally added content | Yes | No | No (but Exempt) <small>Exemptions</small> | Missing |
|---|--|-----|----|--|---------|

- All declarations without an exemption which were previously set to compliance = Yes, will be set to compliance = missing to take into account the change in threshold and will require re-declaring in BOMcheck

Other Restricted or Declarable Substances

In France, Order of August 30, 2023 relating to the identification of dangerous substances in products generating waste requires consumer information relating to the presence of a dangerous substance when it is present in a concentration greater than 0.1% by weight in a substance, mixture or article.

In response the following substance has been added to the Other Restricted and Declarable Substances list in BOMcheck.

Cholecalciferol (CAS: 67-97-0) with a threshold of >0.1% w/w in supplied articles

This substance is primarily used in vaping cartridges for e-cigarettes so it is unlikely to appear in most products.

Extended EU Regulatory Data Capture

The screenshot displays the 'Regulatory Compliance Declaration' (RCD) form in the BOMcheck application. A popup window titled 'Extended EU Regulatory Data Capture' is overlaid on the form, specifically for 'EU ESRs E2-5 & Taxonomy Regulation'. The popup instructs the user to enter the total concentration w/w of the article or total maximum mass (mg) for various substance categories. The categories and their corresponding input fields are:

- Bis(2-ethylhexyl) phthalate (DEHP): 0.10001% (with a 'Concentration Not Known?' button)
- formaldehyde and formaldehyde releasers: 0.1% (with a 'Concentration Not Known?' button)
- Hexachlorobenzene: 0.1% (with a 'Concentration Not Known?' button)
- Cadmium in all batteries: 0.1% (with a 'Concentration Not Known?' button)
- Barium diboron tetraoxide: 0.1% (with a 'Concentration Not Known?' button)
- Ethylene Oxide: 0.1% (with a 'Concentration Not Known?' button)
- Rare earth minerals (g): 1.0 (with a 'Mass Not Known?' button)

The popup also includes 'Back' and 'Save & Continue' buttons at the bottom. The background RCD form shows various regulatory sections like 'RoHS Restrictions', 'REACH Restrictions', and 'Battery Restrictions'.

Popup form will display to collect the required data for all substances where compliance = no.

Required data = total concentration (default) or total maximum mass (in some instances, e.g. Rare Earth Minerals) for substance categories where compliance = no.

All form fields are required to be filled out before the user can progress to the next RCD step.

As the user may not know the concentration or mass then each substance category input should have a “Concentration Not Known” OR a “Mass Not Known” button which will populate the data input with the default over-threshold value.

Process will be separated from all other additional data capture which is aligned with specific substance regulations. Where the data has already been captured it will be pre-populated.

EU ESRS E2-5 & EU Taxonomy Regulation (DNSH)

EU ESRS E2-5: Pollution Reporting – [Link Here](#)

- Objective:** Focuses on specific environmental, social and governance (ESG) metrics that companies need to report.
- Reporting Requirements:**
 - Presence and management of substances of concern and very high concern
 - Impact of substances on air, water, and soil.

EU Taxonomy Regulation (DNSH) – [Link Here](#)

- Objective:** Classify environmentally sustainable activities.
- DNSH Principle:** Activities must not harm any environmental objectives.
- Environmental Objectives:**
 - Climate change mitigation/adaptation
 - Water and marine resource protection
 - Circular economy transition
 - Pollution prevention
 - Biodiversity protection and restoration

Reporting Requirements: Companies need to meet specific technical criteria for determining whether that economic activity causes no significant harm to any of the other environmental objectives.


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 from the 22nd ATP and new SVHCs.

Declaration required

- Action is only required for parts used in medical devices
- The entry for CMR 1A & 1B substances in the RCD tool will be 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 downloaded [here](#) or 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 |
|--|---|---|-----|----|---------|

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 update an individual Regulatory Compliance Declaration (RCD)