

ECHA adds nine new substances to the candidate list (SVHC list).

TÜV Rheinland LGA Products - Information

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On January 17, 2023, the European Chemicals Agency (ECHA) extended the Candidate List of Substances of Very High Concern (SVHC) by nine entries.

With this latest addition, the Candidate List, which is typically updated twice a year, now contains 233 SVHCs that may have serious effects on human health and/or the environment.

Some of these entries refer to groups of chemicals, which actually increases the total number of chemical substances concerned (> 450 substances).

Once a substance has been included in the candidate list, companies must comply with their legal obligations.

Article 33 (1) obliges manufacturers and importers of articles (products) to inform their customers about the presence of SVHCs above 0.1 % by weight in their products and to provide information on the safe use of the product.

Notification of SVHCs to ECHA's Substances of Concern in Products (SCIP) database is also required under the Waste Framework Directive (WFD).

NEW SVHC

Detailed information on the individual substances, areas of application and further notes can be found on the following pages.

Substance name(n)	CAS No	Application areas
1,1'-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene]	37853-59-1	Flame retardants in electrical products
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)	79-94-7	Flame retardants in electrical products
4,4'-sulphonyldiphenol (Bisphenol S – BPS)	80-09-1	Production of pulp, paper, textiles, leather or fur and chemicals
Barium diboron tetraoxide	13701-59-2	Paints and coatings
Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	-	Flame retardants and plasticizers for polyvinyl chloride, etc.
Isobutyl 4-hydroxybenzoate	4247-02-03	Food additives and preservatives
Melamine	108-78-1	Polymers and resins, adhesives and sealants
Perfluoroheptanoic acid and its salts	-	Fluoropolymers / coating systems
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	473-390-7 (EC Number)	a.o. electrotechnical applications

FURTHER INFORMATION ABOUT THE NEW SVHC

1. 1,1'-[ethane-1,2-diylbisoxo]bis[2,4,6-tribromobenzene]

Reason for inclusion: vPvB (very persistent and very bioaccumulative, Article 57e)

BTBPE is a brominated flame retardant used primarily in applications where thermal stability at high processing temperatures is important. Common applications include electrical and electronic equipment (computers, televisions and mobile phones), construction materials and personal protective equipment.

Note

When testing electrical products for flame retardants according to RoHS, BTBPE can be identified as a brominated flame retardant. The use of BTBPE is permitted under RoHS.

It is unusual that this substance is not registered in the EU and yet it is included in the candidate list. This indicates its use in imported products.

2. 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)

Reason for listing: Carcinogenic (Article 57a)

TBBPA is commonly used as a reactive flame retardant in epoxy-based printed circuit boards, where it is present in trace amounts of less than < 0.1%. It is used as an additive flame retardant in thermoplastic polymers for common applications in electrical and electronic equipment, such as ABS plastic housings.

Note

When testing electrical products for flame retardants under RoHS, TBBPA can be identified as a brominated flame retardant. The use of TBBPA is permitted under RoHS.

3. 4,4'-sulphonyldiphenol (Bisphenol S - BPS)

Reason for listing: Toxic for reproduction (Article 57c); Endocrine disrupting properties (Article 57(f) - environment); Endocrine disrupting properties (Article 57(f) - human health)

Like bisphenol A, bisphenol S is one of many bisphenols and a monomer/feedstock for the production of polycarbonates, resins, epoxy resins and related coating systems and adhesives. Traces of free bisphenols (monomers) in the range of 1-100 mg/kg are still present in these polymers in the finished material if these plastics have been produced/cured/polymerized according to the state of the art. It is therefore not to be expected that the content of 0.1 % free bisphenols in the final product will be exceeded.

Note

Testing for free bisphenol content in the above polymers does not appear to be necessary for the reasons described, as the content is negligible at around 0.1%.

There are individual applications where bisphenol S (and others) are used in non-polymerized, free form, e.g. thermal transfer paper (sales slips). In these cases, the free bisphenol content is well > 0.1 %. According to entry 66 of Annex XVII REACH, the use of bisphenol A in thermal transfer papers will no longer be allowed as of 2016.

Attention should also be drawn to the current proposal to restrict bisphenol A and other bisphenols of similar environmental concern. The proposed limit of 10 mg/kg is exceeded by many of the polymers concerned. A ban would have far-reaching consequences. Please also compare our customer information "Proposal to restrict Bisphenols in the EU" from November 2022¹.

¹ <https://www.tuv.com/regulations-and-standards/en/eu-proposal-to-restrict-bisphenols-in-the-european-union.html>

4. Barium diboron tetraoxide

Reason for inclusion: Toxic to reproduction (Article 57c)

The white, sparingly water-soluble barium borate is used as a pigment in paints and coatings. The alkaline properties make it additionally corrosion-protective and biocidal.

Note

Levels above 0.1 % are not expected in common consumer products. When used in paints, coatings and adhesives, it can be assumed that levels of > 0.1 % in the paint coat/adhesive layer will result in levels of < 0.1 % in the product.

5. Bis(2-ethylhexyl) tetrabromophthalate (TBPH) covering any of the individual isomers and/or combinations thereof

Reason for inclusion: vPvB (very persistent and very bioaccumulative, Article 57e)

TBPH is one of several brominated phthalates used as flame retardants. The main use of this group of substances is as flame retardants in polyurethane foams. Furthermore, the use in PVC as plasticizer with additional flame retardant properties is known. Thus, the use in cable insulation, carpeting, fabrics, wall coverings and polyurethane foam is possible when flame retardant properties are required.

Note

We recommend testing for this flame retardant when using PVC, PU foams and PU synthetic leathers if there is evidence of flame retardant treatment or if flame retardant properties are required. It should also be tested for when recycled materials from unknown sources are used.

6. Isobutyl 4-hydroxybenzoate

Reason for inclusion: Endocrine disrupting properties (Article 57(f) - human health)

Isobutyl 4-hydroxybenzoate has been used as an additive for food and as a flavoring agent. It is also known to be used as a preservative in cosmetic products, but has not been permitted for several years.

Note

The substance is not expected to be present in levels above 0.1 % in common consumer products.

7. Melamine

Reason for inclusion: Equivalent level of concern having probable serious effects to human health (Article 57 f – human health, environment)

It is interesting to note that the justification focuses on the persistent, bioaccumulative and mobile properties of the substance, although these are not described in the legal basis.

Melamine is a starting material for various polymerization reactions leading to different resins.

The main application is the production of formaldehyde-based resins. These resins are not only used in the well-known "melamine tableware" and "bamboo cups", but are even more commonly found in electrical appliances (circuit boards, components), adhesives, coatings for components in machines and vehicles, wood materials (binders, coatings), building materials (insulation boards), coating systems/finishes for textiles, tanning agents for leather, and abrasives (cutting disks, scouring disks, sandpaper). The resins are suitable for these applications because they are non-thermoplastic (do not deform when exposed to heat), relatively hard, inexpensive and have low flammability.

Given the large number of applications, the SVHC listing will trigger a number of notifications along the supply chain (Art. 33 1 and 2), notifications (Art. 7.1) and entries in the SCIP database.

The situation may escalate if melamine is added to the Annex XIV authorisation list in a further step. This is likely to result in users in the EU no longer being able to use the existing substances in this way.

Analysis of melamine:

From an analytical point of view, the difficulty of determining the exact content of non-polymer-bound, monomeric melamine in a melamine resin should be pointed out. It can be assumed that intensive extraction procedures (acidic, alkaline, with solvents) will break down the polymer and produce more results. If the extraction is not sufficient, it can be assumed that fewer findings will be obtained. The development of a suitable method, if necessary, has been started.

A standardized method for the determination of monomeric melamine in a melamine resin is not known. It is also not known how the authorities can control a value of 0.1 % in corresponding products.

Note

Since we are currently unable to offer testing for monomeric melamine in a melamine resin, we recommend that you obtain confirmation from the resin manufacturer that the monomeric melamine content is less than 0.1%.

8. Perfluoroheptanoic acid and its salts (PFHxA)

Reason for inclusion: Toxic for reproduction (Article 57 c); Persistent, bioaccumulative and toxic (Article 57 d); Very persistent and very bioaccumulative (Article 57 e); Equivalent level of concern having probable serious effects to human health (Article 57 f – human health); Equivalent level of concern having probable serious effects to the environment (Article 57 f – environment)

Perfluoroheptanoic acid is not a component of materials/polymers in its own right, like plasticizers or other additives. Rather, it is a starting material, an additive that reacts in a variety of ways with other materials, polymers, carriers to form a variety of fluoropolymers or a coating. As is often the case in chemistry, these reactions are not complete and only residues, often only traces, remain in the final product.

Note

Currently, we do not see the need to test for a value of 0.1 % perfluoroheptanoic acid in common consumer products. Please note that in the context of many customer requirements (RSL) the use of this substance group is regulated.

Ongoing restriction proposal for perfluorohexanoic acid (PFHxA)

Note the current proposed restriction on perfluorohexanoic acid (PFHxA), its salts and precursors. In light of these developments, you should be aware of which of your products contain these materials and be prepared for a possible ban.

The C8 chemicals previously used have been replaced in recent years by shorter-chain and less critical C6 chemicals such as PFHxA. In most cases, these are suitable for maintaining the previous product properties.

In the manufacture of fluoropolymers (e.g. PTFE or FKM) C6 chemicals are used as emulsifiers. As described above, residual amounts of PFHxA are to be expected. At the limit value discussed, it is expected that fluoropolymers can no longer be manufactured and placed on the market. Alternatives are not expected to be available for all applications.

9. Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine

Reason for listing: vPvB (very persistent and very bioaccumulative, Article 57e)

This vPvB substance is a PFAS group substance, also known as "hydrofluoric acid, reaction products with 4-(1-methylethyl) morpholine" and is predictably so synthesized. The substance is electrically non-conductive, thermally and chemically stable and is used in technical and electrotechnical applications.

Note

The substance is not expected to be present in levels above 0.1% in common consumer products.

Further information on current legal changes can also be found on our homepage at www.tuv.com or <https://www.tuv.com/regulations-and-standards/en/>.

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