

About the polymer-based products supplied by **POLYTRON Kunststofftechnik GmbH & Co. KG** (POLYTRON) we could give following information:

We herewith confirm, to the best of our knowledge and according to the actual status of technology, that hazardous substances like the below listed ones are neither being used nor added nor found during the production of polymers, semi-finished plastic shapes and plastic parts made from these (plastic products):

- Asbestos-containing fibres and fillers
- Bisphenol A – CAS: 80-05-7 (BPA) ⁱ
- Dimethyl fumarate – CAS: 624-49-7 (DMF < 0.1 mg/kg)
- halogenated hydrocarbons (CFCs, HCFCs)
- Hexachlorobuta-1,3-diene – CAS: 87-68-3 (HCBd)
- Commodities and products associated with deforestation and forest degradation and reaping
- Conflict minerals ⁱⁱ
- Latex ⁱⁱⁱ
- Pentachlorobenzene Thiol – CAS: 133-49-3 (PCTP)
- Perfluorooctane Sulfonate – CAS: 1763-23-1 (PFOS)
- Perfluorooctanoic acid – CAS: 335-67-1 (PFOA)
- Phenol, Isopropylated, Phosphate (3:1) – CAS: 68937-41-7 (PIP 3:1)
- Phthalates (BBP <0.1%, DBP <0.1%, DEHP <0.1%, DIBP <0.1%, DIDP, DINP, DNOP, DOP)
- Polybrominated biphenyls (PBB <0.1%)
- Polybrominated diphenyl ethers (PBDE <0.1%)
 - Decabromodiphenyl Ether – CAS: 1163-19-5 (DBDPE)
 - Octabromodiphenyl Ether – CAS: 32536-52-0 (OBPDE)
 - Pentabromodiphenyl Ether – CAS: 32534-81-9 (PBDPE)
- Polychlorinated Biphenyls (PCBs)
- Polycyclic aromatic Hydrocarbons (PAHs)
- Heavy metals (lead <0.1%, cadmium <0.01%, chromium-(VI) <0.1%, mercury <0.1%)
- Silicone ^{iv}
- Substances of animal origin (ADI) ^v
- Titanium Dioxide – CAS: 13463-67-7 ^{vi}
- 2,4,6-Tri-tert-butylphenol – CAS: 732-26-3 (2,4,6-TTBP) 2,4,6-Tri-tert-butylphenol

As due to the best of our knowledge the above listed substances are not being used during production chain or are not used in prohibited quantities, consequently limiting values are not monitored!

The products we deliver thus meet the following requirements, among others:^{vii}

Note: The semi-finished plastic shapes and resins supplied by us as well as the components (plastic products) made thereof are neither polymers nor substances within the meaning of most of the regulations listed below but are considered end products and therefore some of them do not fall within their scope. However, we would like to support our customers in the supply chain to comply with the relevant regulations and therefore provide the information listed below.

- 1994/62/EC – Packaging and Packaging Waste Directive
- 2000/53/EC – End-of-Life Vehicles Directive (ELV)
- 2003/11/EC – Directive on the restriction of certain dangerous substances (pentabromodiphenyl ether, octabromodiphenyl ether)

POLYTRON Kunststofftechnik GmbH & Co. KG

An der Zinkhütte 17
51469 Bergisch Gladbach
Fon: +49 2202 1009 0
Fax: +49 2202 1009 333
Mail: info@polytron-gmbh.de
www.polytron-gmbh.de

Commerzbank AG | IBAN: DE51 3704 0044 0270 3007 00 | BIC: COBADE33XXX
Deutsche Bank AG | IBAN: DE96 3307 0090 0844 2055 00 | BIC: DEUTDE33XXX
Pers. haftender Gesellschafter: POLYTRON Kunststofftechnik Verwaltungs-GmbH
Amtsgericht / Local Court: Köln / Cologne - HR B 47113
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- 2005/69/EC – Directive on the restriction of certain hazardous substances (polycyclic aromatic hydrocarbons in plasticiser oils and tyres)
- 2005/84/EC – Directive on the restriction of certain dangerous substances (phthalates in toys and childcare articles)
- 2006/122/EC – Directive on the restriction of certain hazardous substances (perfluorooctane sulfonates)
- 2011/65/EU – Directive on the restriction of the use of certain hazardous substances in electrical or electronic equipment (RoHS) ^{viii}
- 2015/863/EU – Directive Amendment of Annex II to Directive 2011/65/EU as regards the list of substances subject to restrictions
- 2009/251/EC – Commission decision not to place or make available on the market products containing dimethyl fumarate (DMF)
- (EC) 1907/2006 – Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) including all modifications and updated SVHC-list ^{ix}
- (EC) 1005/2009 – Regulation on substances that deplete the ozone layer
- (EC) 1272/2008 – Regulation on classification, labelling and packaging of substances and mixtures^x
- (EU) 2017/821 – Regulation laying down obligations for the trade of tin, tantalum, tungsten, their ores and gold from conflict zones and Title XV (Sec. 1502) of the Dodd–Frank Act ^{xi}
- (EU) 2017/1000 – Regulation amending Annex XVII to Regulation (EC) 1907/2006 concerning perfluorooctanoic acid (PFOA), its salts and PFOA precursor compounds
- (EU) 2019/1021 – Persistent Organic Pollutants Regulation ^{xii} and Section 6 (h) of the Environmental Protection Agency's Toxic Substances Control Act 1976 (TSCA) ^{xiii} and Office of Environmental Health Hazard Assessment (OEHHA) listed substances - California Proposition 65^{xiv}
- (EU) 2023/1115 - Certain commodities and products associated with deforestation and forest degradation and repealing (EUDR)^{xv}

Comments on the context of the information obligation:

- ⁱ Exceptions are our products made from Polyetherimide (PEI), Polysulfone (PSU) and polycarbonate (PC). These polymers are polymerized from, among other things, the monomer bisphenol A (BPA). After polymerization, small amounts of Monomer constituents may remain in the product! For use in the EU, the "Union List of Approved Monomers (...) in the production of plastics" in accordance with Regulation (EU) 10/2011, the use of BPA is allowed up to a specific migration value (SML) of 0.6 mg/kg. However, these products have not been evaluated for use in contact with infant formula and/or human (breast) milk. **The limiting value of BPA of above subscribed products has to be specified on the final product!**
- ⁱⁱ The conflict minerals are Tantalum (coltan), tungsten, tin and their ores as well as gold counted (see also comment X). The statements made here expressly do not apply to the means of our production equipment, as their complexity makes it impossible for us to evaluate them.
- ⁱⁱⁱ During the production and fabrication processes latex gloves could be used. Residues of these gloves might remain on the surface of the products but generally can be removed by using dedicated cleaning processes.
- ^{iv} During the production processes (e.g., extrusion, injection molding, pressing) silicone spray could be used as an external lubricant. Residues of this spray might remain on the surface but generally will be removed during secondary operations and further on can be removed by using dedicated cleaning processes.
- ^v Basically, polymers may contain additives from derivatives of fatty acids of animal origin. But it has to be considered that during the complete manufacturing process – from producing the additives to the processing of plastics and the subsequent finishing and treatment – the additives are re-exposed to temperatures exceeding 200 °C for several hours. Due to this production process, it is difficult to imagine that additives from derivatives of fatty acids of animal origin in plastics can redistribute or spread bovine spongiform encephalopathy (BSE)/ transmissible spongiform encephalopathy (TSE). However, as the transmission of BSE/TSE by plastic additives is not expected there is no strict control of prescribed limit values! Therefore, it remains in the responsibility and duty of the user or buyer to control quality requirements complying with allowed limit values or legal regulations.

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- vi In the production of raw materials, titanium dioxide is partly used, also in quantities > 1%. Titanium dioxide in powder form is classified as "suspected carcinogenic by inhalation". However, the titanium dioxide is firmly integrated into the products we supply. A release of individual titanium dioxide particles is therefore unlikely, even during mechanical processing – as long as the general dust limit values are complied with.
- vii Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) already ensures in principle that only those substances are manufactured, placed on the market or used that do not adversely affect human health or the environment. **Please refer to our separate REACH-Information!**
- viii In conjunction with this directive, we often get inquiries to the compliance of our products with directive 2002/96/EC on waste electrical and electronic equipment (WEEE). This directive provides rules for the prevention of waste in electrical and electronic equipment as well as the recycling and other forms of recovery of such waste to reduce the disposal of waste. As producer of semi-finished plastics and parts made thereof, we could make no statements to the compliance of our products with this specific directive.
- ix Exceptions are our products made from Polyvinyl Chloride (PVC). The following given PVC-types: PVC-U (un-plasticized), PVC-C (chlorinated), PVC-HI (impact modified), PVC-P (plasticized) as well as PVC-E (expanded) may contain more than 0,1% of the organotin compounds Dibutyltin (DBT) and Dioctyltin (DOT) listed in the ECHA candidate list of substances of very high concern – SVHC. **The limiting values of DBT and DOT of above subscribed PVC-products has to be specified on the final product!**
- x According to our suppliers, hazardous substances, carcinogenic, mutagenic or toxic to reproduction (CMR substances = carcinogenic, mutagenic and toxic to reproduction) are used in the production of raw materials in accordance with Annex VI of this regulation. These are usually completely consumed during the production of raw materials and can only be detected in trace amounts – if at all (see also comment xiv).
- xi Regulation (EU) 2017/821 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas supplemented with regulations (EU) 2019/429 and (EU) 2020/1588 pledge European companies to take responsibility for their supply chain and take actions to prevent conflict financing and human rights violation by dealing with so called conflict resources. Following this certain threshold values for tantalum- and niobium-ores as well as their concentrates, gold, gold-ore and their concentrates, tin-oxides and -hydroxides, tantalum and tantalum-carbides, tin-ores and their concentrates, tungsten-ores and their concentrates as well as tungsten-oxide and -hydroxide, tin-chloride, tungsten, wolframite, columbite-tantalite and cassiterite were given. Comparable with this legislation the Dodd-Frank-Act Title XV (Sec. 1502) pledges US-companies to disclosure whether they use so called conflict-materials originating in or near the Democratic Republic of the Congo and which are benefiting armed groups in the area, Since the substances mentioned are not used, the presence of these substances is not monitored!
- xii Regulation (EU) 2019/1021, the so-called POP Regulation (POP = persistent organic pollutants), sets the requirements of the Stockholm Agreement and the POP protocol of the UNECE into European law replacing Regulation (EC) 850/2004. It has been adapted by further regulations (2020/1203, 2020/1204, 2021/115, 2021/277 and 2022/2400) over the years and essentially lists substances subject to restrictions (Annex II) and release reduction provisions (Annex III). Provisions for waste management (Annexes IV and V) are also laid down. Since the substances mentioned are not used, the presence of these substances is not monitored!
- xiii The Toxic Substances Control Act 1976 becomes by Frank R. Lautenberg Chemical Safety for the 21st Century Act concretized. This obliges the EPA (U.S. Environmental Protection Agency) to accelerate action to reduce certain persistent, bio accumulative and toxic Chemicals (PBT). The regulations are partly analogous to the corresponding European directives and regulations (see also comments VII and XII).
- xiv The California Proposition 65 – Safe Drinking Water and Toxic Enforcement Act requires manufacturers to provide a clear and reasonable warning about potential exposure to Office of Environmental Health Hazard Assessment (OEHHA) listed substances from their products' intended or foreseeable use. Polytron products according to this information are manufactured for engineering purposes and are not for direct use by consumers. OEHHA listed substances are neither intentionally introduced during the production of the raw materials nor during the manufacture of the products. However, products may contain trace amounts of OEHHA listed substances bound within the polymer matrix. **Please refer to our separate California Proposition 65-Information!**
- xv Packaging materials used may still contain corresponding substances, but in future they will be replaced by substances that comply with the regulation in accordance with the transitional periods.