



WITTENBURG

Your partner in TPE, medical & food compounds

PSB chemicals, regulations and standards (August 2018)

Phthalates

Directive 2005/84/EC restricting the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles)

This Directive states that certain phthalates shall not be used as substances or as constituents of preparations, at concentrations greater than 0.1 % by mass of the plasticised material, in toys and childcare articles. The phthalates listed are the following:

- **DEHP (Diethylhexylphthalate)**
- **DBP (Dibutylphthalate)**
- **BBP (Benzylbutylphthalate)**
- **DINP (Di-isononylphthalate)**
- **DIDP (Di-isodecylphthalate)**
- **DNOP (Di-n-octylphthalate)**

We do not analyze our products for the presence of the above phthalates. However, these substances are not used as a raw material, nor are they added during the manufacturing of our Cawiton TPE materials.

Polycyclic Aromatic Hydrocarbons (PAH)

Commission Regulation 1272/2013/EC, amending REACH Annex XVII of 1907/2006/EC; new specifications for Polycyclic Hydrocarbons (PAHs) under the German voluntary GS-Mark, issued by the German Committee on Product Safety, replacing ZEK 01.4-08 per July 1, 2015.

Wittenburg do not analyze Cawiton TPE grades for the presence of the 8 Polycyclic Aromatic Hydrocarbons defined in the above EU Regulation and also for the presence of the 18 PAHs described in the GS-Mark ZEK 01.4-08 and the newly adopted guidelines. The 18 PAH's involved are the following:

Naphtalene; Acenaphthylene; Acenaphthene; Fluorene; Phenanthrene; Anthracene; Fluoranthene; Pyrene; Chrysene; Benzo[a]anthracene; Benzo[b]fluoranthene; Benzo[k]fluoranthene; Benzo[j]fluoranthene; Benzo[a]pyrene; Benzo[e]pyrene; Indeno[1,2,3-cd]pyrene; Dibenzo[a,h]anthracene; Benzo[g,h,i]perylene.

These PAH's are not used as ingredients in the formulation of Cawiton TPE compounds. Based on information from our raw material suppliers, including particular PAH analytical data from our resin suppliers, it is not to be expected that any of these PAH's would be present in this product in concentrations exceeding the limits indicated. Analysis for traces of PAH's is not performed on our final products, however.

Heavy metals

Directive 94/62/EC on packaging and packaging waste (including Directive 2013/2/EU amending Annex I)

The chemical composition of Cawiton TPE grades meets the relevant requirements of Directive 94/62/EC (as amended) on packaging and packaging waste. The sum of the concentration **Cd**, **Cr(VI)**, **Hg** and **Pb** in these products is not expected to exceed 0.01 wt. % (100 ppm).

USA Consumer Safety Improvement Act (CPSIA section 101) restricting the Lead (Pb) content in children's products

During the manufacturing process of our Cawiton TPE materials we do not intentionally add any **Lead (Pb)** or **Pb-containing substances**. Based on our knowledge of the raw materials and the manufacturing process, it is unlikely that Lead (Pb) would be present in this product in concentrations exceeding the legislation limits mentioned in CPSIA Section 101. Analysis for traces of Pb is not performed on our final products, however.



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China RoHS (SJ/T11363-2014, updated version of -2006) on the use of toxic substances in electronic products

This Directive states a maximum allowed concentration limit of 0,1 weight percent (= 1000 ppm) for: **Lead (Pb); Mercury (Hg); Hexavalent Chrome (CrVI); Polybromated Biphenyl (PBB); Polybromated Diphenylether (PBDE)** and a maximum allowed concentration limit of 0,01 weight percent (= 100 ppm) for **Cadmium (Cd)**. Based on our knowledge of the raw materials and the manufacturing process, it is not to be expected that any of these elements would be present in Cawiton TPE grades in concentrations exceeding the legislation limits. Analysis for traces of these elements or substances is not performed on our final products, however.

Directive of End of life Vehicles (ELV) (2000/53/EC; (EU) 2016/774 amending Annex II to 2000/53/EC)

The chemical composition of the Cawiton TPE grades meets the relevant requirements of Directive 2000/53/EC (as amended) on the End of Life Vehicles (ELV). Based on information from our raw material suppliers, the concentration of Cr(VI), Hg and Pb in Cawiton grades is not expected to exceed 0.1 wt. %, and the concentration of Cd is not expected to exceed 0.01 wt. %. Analysis for traces of these elements is not performed on our final products, however.

Environmental pollutants

Commission Regulation (EU) 2015/2030 amending (EC) No. 850/2004 on Persistent Organic Pollutants (Compliance with Stockholm Convention)

Wittenburg do not intentionally add any Persistent Organic Pollutants (POP's) during the manufacturing process of Cawiton grades – ref. POP's as mentioned in Annexes are not used in the manufacture A, B and C of the Stockholm Convention, including the amendments to these annexes.

Directive 1005/2009/EC on substances that deplete the ozone layer

No ozone depleting substances such as **CFC's, HCFC's, HBFC's, Halons, CCl₄**, and **Trichloroethane** are intentionally used in the formulations of the Cawiton TPE materials. The absence of these substances has not been verified by tests, however.

Directive 2012/19/EU (Waste Electrical & Electronic Equipment, WEEE, repealing 2002/96/EC)

With respect to Annex VII, no ingredients are intentionally used in the formulation of Cawiton TPE grades, which require selective waste treatment.

Volatile Organic Compounds (VOC's): Swiss SR 814.018 (Verordnung über die Lenkungsabgabe auf flüchtigen organischen Verbindungen - VOCV) - VOC's according to Annexes 1 & 2 < 3 wt%

CMR substances

Statement California Proposition 65 (Chemicals known to have carcinogenic properties or reproductive toxicity) (latest update May 25, 2018).

Herewith we confirm that no substances listed in the above **California Proposition 65** (CALPROP) are intentionally used in the formulations of Cawiton materials, and from supplier data we have no reason to believe that the raw materials used would include any substances from this CALPROP list.

The absence of these substances has not been verified by tests, however.

It is to be noted that due to

1. the potential presence of solvent/monomer/starting material traces in the raw materials used and/or
2. thermal degradation products generated in the compounding process at Wittenburg and/or
3. thermal degradation products formed during the injection-moulding process by the producer of the final article, small traces of CALPROP listed chemicals could theoretically be found in the final article.

Therefore, it is unavoidable that the final material processor in the supply chain will need to verify CALPROP compliance for the final articles *).



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*) For “safe harbor” levels, the Office of Environmental Health Hazard Assessment (OEHHA) recently provided a guidance document with No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity
<https://oehha.ca.gov/media/downloads/proposition-65/general-info/safeharborlist041218.pdf>

Allergenic substances

The food ingredients listed in Annex II of Regulation No.1169/2011 are not used in the formulations of Cawiton (TPE) compounds. Cawiton materials are not analyzed for allergens, however.

Halal Certification; Kosher Certification

Cawiton TPE materials are not certified Halal or Kosher.

Animal origin ingredients and Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) – “Mad Cow“

In general Wittenburg aims to avoid using of (and physical contact with) raw materials containing animal origin species during the manufacturing of Cawiton TPE grades; however this cannot always be avoided. In such cases where tallow derived materials are present in the raw materials used in the manufacturing of Cawiton TPE grades, these tallow based substances fulfil the requirements laid down in the Regulations 1069/2009/EC and 142/2011/EC, and the “Note for Guidance EMEA/410/01, rev. 3“.

We therefore can state that, to the best of our knowledge, our Wittenburg Cawiton TPE grades can be considered safe to use with respect to BSE and TSE transmissions.