



XUNFENG

医疗和食品领域，您的TPE合作伙伴

珠海巽丰特种塑料有限公司

A member of Wittenburg Group

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Xunfeng Cawiton PSB chemicals, regulations and standards (August 2018)

巽丰 Cawiton 材料化学物质规范与标准（2018年8月）

Phthalates

邻苯二甲酸盐

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

2005/84 / EC 指令用于限制某些危险物质和制剂的销售和使用（例如玩具和儿童护理用品中的邻苯二甲酸酯）

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:

指令中规定，某些邻苯二甲酸酯不得用作物质载体或制剂成分，在类似玩具和儿童护理用品的塑化材料成分中，其浓度不得超过 0.1%。所列邻苯二甲酸酯如下：

- **DEHP (Diethylhexylphthalate)**
- 邻苯二甲酸二乙基己基酯(DEHP)
- **DBP (Dibutylphthalate)**
- 邻苯二甲酸二丁酯 (DBP)
- **BBP (Benzylbutylphthalate)**
- 邻苯二甲酸丁基苄酯 (BBP)
- **DINP (Di-isononylphthalate)**
- 邻苯二甲酸二异壬酯 (DINP)
- **DIDP (Di-isodecylphthalate)**
- 邻苯二甲酸二异癸酯(DIDP)
- **DNOP (Di-n-octylphthalate)**
- 邻苯二甲酸二正辛酯 (DNOP)

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. 我们并未分析我们的产品是否含有上述邻苯二甲酸盐。但我们没有采用这些物质用作原材料，在制造 Cawiton TPE 材料时也未添加。

Polycyclic Aromatic Hydrocarbons (PAH)

多环芳烃 (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.

欧委会法规 1272/2013/EC, 1907/2006/ECREACH 附件 17 修正案;

德国非官方自愿 GS 标志下的多环芳烃新规范，由德国产品安全委员会发布，于 2015 年 7 月 1 日替代 ZEK 01.4-08。

Xunfeng 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:

巽丰没有分析 Cawiton TPE 材料中是否出现上述欧委会法规中提及的 8 种多环芳烃、GS-Mark ZEK 01.4-08 中提及的 18 种 PAH 和最近通过的指导方针。涉及的 18 种 PAH 如下：



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NaPhthalene; 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.

萘; 芘烯; 芘; 芴; 菲; 蒽; 荧蒽; 苝; 蒾; 苯并[a]蒽; 苯并[b]荧蒽; 苯并[k]荧蒽; 苯并[j]荧蒽; 苯并[a]苝; 苯并[e]苝; 茚并[1,2,3-cd]苝; 二苯并[a,h]蒽; 苯并[g,h,i]苝

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.

在 Cawiton TPE 材料的原料中, 这些 PAH 都未用作原料。根据我们的原材料供应商的信息, 包括树脂供应商的特定 PAH 分析数据, 我们的产品中的任何 PAH 均不会超出所示的浓度限值。不过我们并未分析最终产品的 PAH 含量。

Heavy metals

重金属

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

关于包装和包装垃圾的 94/62 / EC 指令 (包括 2013/2/EU 指令修正附件 1)

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).

Cawiton TPE 材料的化学成分符合 94 / 62 / EC 指令 (已修订) 对包装和包装垃圾的相关要求。这些产品中的镉、六价铬、汞和铅的浓度之和不超过 0.01 wt. % (100 ppm)。

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

美国消费品安全改进法(CPSIA第101部分)对儿童产品中的铅含量进行限制

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.

在我们Cawiton TPE材料的生产过程中, 我们不会有意添加**铅 (Pb)** 或**含铅物质**。根据我们对原材料和制造工艺的了解, 产品中的铅浓度不会超过CPSIA第101节中规定的浓度。不过我们并未分析最终产品中的铅含量。

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

中国 (SJ / T11363-2014, 更新版本-2006) 关于电子电气产品中使用有害物质的限制指令 (RoHS)

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



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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.

该指令规定, 最大允许的浓度极限为 0.1 重量百分比 (= 1000 ppm), 适用于: 铅 (Pb); 汞 (Hg); 六价铬 (CrVI); 多溴联苯 (PBB); 多溴联苯醚 (PBDE) 和最大允许浓度限值为 0.01 重量百分比 (= 100 ppm), 适用于, 镉 (Cd)。根据我们对原材料和制造工艺的了解, 我们相信, 在 Cawiton TPE 材料中, 这些元素中的任何一种都不会超过法定限值。不过我们并未对最终产品进行此类元素或物质的分析。

Directive of End of life Vehicles (ELV) (2000/53/EC; (EU) 2016/774 amending Annex II to 2000/53/EC) 针对报废汽车的指令 (ELV) (2000/53 / EC); (EU) 2016/774 修正 2000/53/EC 附件 II)

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.

Cawiton TPE 材料的化学成分符合报废车辆 (ELV) 2000/53 / EC 指令 (修订版) 的相关要求。根据我们的原材料供应商的信息, Cawiton 材料的六价铬、汞和铅的浓度预计不会超过 0.1 wt. %, 镉的浓度预计不超过 0.01 wt. %。但是, 我们并未对最终产品进行这些元素的分析。

Environmental pollutants

环境污染

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

欧盟委员会条例 (EU) 2015/2030 修订 (EC) 850/2004 号持久性有机污染物的持续性 (遵循斯德哥尔摩公约)

Xunfeng 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.

在 Cawiton 材料的生产过程中, 巽丰不会有意添加任何持久性有机污染物 (POP's) — 附件中提及的参考物未用于斯德哥尔摩公约的 A、B 和 C 制造中, 包括这些附件的修正案。

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

关于消耗臭氧层物质的指令 1005/2009 / EC

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.

在 Cawiton TPE 材料的原料中, 没有使用如 CFC、HCFC、HBFC、二氟二氯甲烷 CCl4 和三氯乙烷的臭氧消耗物质。不过我们并未实验验证是否有这些物质存在。

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

2012/19 / EU 指令 (废弃和报废的电子电气设备, 2002/96 / EC 取消)

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

就附件 7 而言, 在 Cawiton TPE 材料的配方中没有使用需要选择性废料处理的原料。

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%

挥发性有机化合物 (VOC's): 瑞士SR 814.018 (Verordnung über die Lenkungsabgabe auf flüchtigen organischen Verbindungen-VOCV) —— 根据附件1和2的内容, VOC's < 3 wt%

CMR substances CMR 物质

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

加利福尼亚州65号提案 (已知具有致癌性或生殖毒性的化学物质) (最近更新于2018年5月25日)。

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.

在此, 我们证实, 上述**加利福尼亚第65号提案 (CALPROP)** 中列出的物质都没有用作Cawiton TPE材料的配方。从供应商的数据来看, 我们相信我们使用的原材料不包括提案中提及的任何物质。

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

不过我们并未检测这些物质是否存在。

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 Xunfeng 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.

需要注意的是, 由于

1. 在所用原料中可能存在溶剂/单体/原料和/或
2. 巽丰在改性工艺中产生的热降解物和/或
3. 成品生产商在注塑过程中形成的热降解物, 理论上可以在成品中发现少量CALPROP列出的化学物

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

因此, 供应链中的最终材料加工商不可避免的需要验证最终产品是否符合CALPROP*).

*) 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

*)对于“安全港”水平来说, 环境健康威海评估办(OEHHA)最近提供了一份关于致癌物质无显著危险因素(NSRLs)以及化学品导致生殖毒性最大允许剂量水平(MADLs)的指导文件。

<https://oehha.ca.gov/media/downloads/proposition-65/general-info/safeharborlist041218.pdf>

Allergenic substances 致敏性物质

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.

Cawiton (TPE) 材料的配方中未使用第 1169/2011 号法规的附件 2 中列出的食品配方。然而我们并未分析 Cawiton 材料中的过敏原。

Halal Certification; Kosher Certification 清真认证; 犹太认证

Cawiton TPE materials are not certified Halal or Kosher.

Cawiton TPE 材料未经清真或犹太的认证。



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Animal origin ingredients and Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) – “Mad Cow” 动物提取原料和牛海绵状脑病（BSE）/传染性海绵状脑病（TSE） - “疯牛病”

In general Xunfeng 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 Xunfeng Cawiton TPE grades can be considered safe to use with respect to BSE and TSE transmissions.

一般来说，巽丰避免在制造 Cawiton TPE 材料时使用（或接触）含有动物源生物种的原材料，但这些不是能完全避免的。

在生产 Cawiton TPE 材料的过程中存在牛脂衍生的原材料时，这些源于牛脂的物质符合 1069/2009/EC、142/2011/EC 法规和《EMEA/410/01 指引第三修正案》中所述的要求。

因此我们能声明，据我们所知，我们巽丰的 Cawiton TPE 产品是可以安全使用的，不会传播 BSE 和 TSE。