



珠海巽丰特种塑料有限公司

XUNFENG

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医疗和食品领域，您的TPE合作伙伴

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Xunfeng Product Stewardship Bulletin (PSB) for Cawiton TPE grades intended to be used for food contact applications (June 2018)

巽丰用于食品接触应用领域的Cawiton® TPE产品管理公告 (PSB) (2018年6月)

Cawiton TPE grades intended for food contact applications comply with the relevant laws and regulations as required. Reference to food contact compliance will generally be made in the Product Data Sheet of the Cawiton grade issued. The “soft” elastomeric components of Cawiton TPE materials may include TPE-S (Styrene Block Copolymers), thermoplastic polyurethanes (TPU), copolyester elastomers (COPE) or polyether block amides (PEBA), and “hard” blend components may include polyolefins (PP, PE), specialty ethylene copolymers (EVA, EMA), or Topas COC. Also paraffinic white oil may be present as extender oil. 用于食品接触应用领域的Cawiton® TPE符合相关法规。将在发布的Cawiton®产品数据表中对食品接触合规进行整体参照。Cawiton® TPE材料的“软”弹性体组分可能包含TPE-S（苯乙烯分段共聚体）、热塑性聚氨酯(TPU)、共聚酯弹性体(COPE)或聚醚嵌段酰胺(PEBA)，“硬”混合共混组分可能包含聚烯烃(PP, PE)、特种乙烯共聚物(EVA, EMA)、或环烯烃共聚物。凡士林白油还可以作为填充油。

Raw material policy

原材料政策

All raw materials used in compounding of Cawiton grades are controlled for compliance with applicable laws and regulations before being approved for use (by document screening, not by analytical verification). Raw material suppliers have the obligation to notify Xunfeng in case of changes in the composition of their product, changes in product properties (as a result of manufacturing process changes or changes in raw material sources), and changes in the regulatory status of their product. No notification is required in case of changes in manufacturing location of the raw materials used.

在批准使用前（通过文件筛选，而不是分析验证），用于Cawiton®材料的所有原材料都按照适用的法律法规进行管控。原材料供应商有义务通知巽丰其产品成分、产品属性（生产工艺改变或原材料来源有变）和管理状况的变化。改变原材料生产地址时无需通知。

Food contact compliance EU

EU的食品接触法规

Commission Regulation (EC) No 1935/2004, so far applicable to polymer pellets, powders and/or flakes.

The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3 must be verified and tested by the producer of the final packaging material.

1935/2004号欧委会法规 (EC)，目前适用于聚合物颗粒、粉末或薄片。食品接触材料的感官特性受转化条件、时间、储存温度和食物类型的影响，因此生产商必须对最终的包装材料按照条款3的规定进行验证和测试。

Commission Regulation (EU) 2011/10 (positive list) as amended by 321/2011/EC (restriction of use of BPA in plastic infant feeding bottles), 1282/2011/EC, 1183/2012/EC, 202/2014/EC, 174/2015/EC, and 1416/2016/EC, 752/2017/EC, 79/2018/EC, 213/2018/EC and 831/2018/EC and respectively, related to Plastic Materials and Articles intended to come into contact with foodstuffs. All monomers, starting substances and additives (incl. optionally paraffinic white oil) used are listed in Annex I of this Directive, related to plastic materials and articles intended to come into contact with foodstuffs. Xunfeng will gather all available supplier information on relevant migration restrictions (SML; QM) and Dual Use additives present and make that available on customer request, to support migration testing.

欧委会法规(EU) 2011/10 (肯定列表) 根据修正的321/2011/EC（限制在塑料婴儿奶瓶中使用BPA）、1282/2011/EC、1183/2012/EC、202/2014/EC、174/2015/EC、1416/2016/EC、752/2017/EC、



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79/2018/EC, 213/2018/EC和831/2018/EC, 其内容与塑料材料和食品接触物品相关。所有使用的单体、起始剂和添加剂（包括可选的凡士林白油）都列在指令的附件1中，其内容与塑料材料和食品接触物品相关。巽丰将收集一切可用的与迁移限制相关的供应商信息（SML;QM）和两用添加剂，并使其符合客户的需求，以便支持迁移测试。

Commission Regulation (EC) 2023/2006 as amended by Commission Regulation (EC) 282/2008, on good manufacturing practice (GMP) for materials and articles intended to come into contact with food. The raw materials selected have been manufactured in accordance with the relevant requirements of Good Manufacturing Practice (GMP) for materials articles intended to come into contact with food. Xunfeng declare that the total delivery process (including material handling, processing, packaging, and transport), as well as the supporting Quality Control and Quality Assurance systems are able to deliver products that can be safely used for hygienic food contact applications, and the general rules on GMP are fulfilled.

欧委会法规(EC) 2023/2006, 欧委会法规 (EC) 282/2008修正案, 内容涉及材料和食品接触物品的良好生产规范（GMP）。所选原材料的生产都遵照了材料和食品接触物品的良好生产规范的相关要求。巽丰声明，整个交付过程（包括原料处理、加工、包装和运输）及质控支持和质量保障系统都能够确保所交付的产品能安全地用于卫生食品接触，并符合GMP的一般规则。

Not Intentionally Added Substances (NIAS)

非有意的添加物质（NIAS）

All our raw material suppliers have performed a risk assessment for NIAS on selected representative grades. Typical NIAS are reaction- and decomposition products from antioxidants, many of them known as "Arvin-substances". Some joint industry studies have shown that none of these "Arvin-substances" are genotoxic and can therefore be classified as "Cramer-class III" allowing a daily consumption of 90 micrograms/person/day.

我们所有的原材料供应商都已经对所选的代表品级进行了 NIAS 风险评估。典型的 NIAS 是抗氧化剂的反应和分解产物，也叫做“Arvin 物质”。一些联合的产业研究表明，这些“Arvin 物质”都没有遗传毒性，因此都能归类为“Cramer 三级”，每日可消耗 90mg/人/天。

The major fractions of NIAS in polyolefins are the oligomers, which are unavoidably formed during polymerisation and cannot be removed. A recent joint study of polyolefin producers demonstrated that oligomers migrating from all types of polyolefins only consist of linear and branched alkanes (POSH) and alkenes (POMH), no cyclic or aromatic compounds were found. The toxicological assessment of such migrants concluded that they are sufficiently characterised by the existing overall migration limit. 聚烯烃中 NIAS 的主要部分是低聚物，其在聚合过程中不可避免地形成并且不能移除。最近对聚烯烃生产商的联合研究表明，所有类型的聚烯烃迁移的低聚物仅由直链和支链烷烃（POSH）和烯烃（POMH）组成，未发现环状或芳香族化合物。对这些析出物的毒理学评估表明，它们充分的表征在现有迁移物限制值中。

It is advisable to process the material according to the recommended temperature range, in order to minimize the generation of NIAS substances. Furthermore, it has to be emphasized that the degree of the generation of NIAS substances, is also influenced by mechanical treatments during conversion steps, and also by mixture with other substances.

建议根据推荐的温度范围加工材料，以尽量减少 NIAS 物质的产生。此外，必须强调的是 NIAS 物质的产生程度也受到转化步骤中的机械加工及所混合的其他物质的影响。

Under article 19 of the (EU) 2011/10, the responsibility for conducting a NIAS risk assessment lies entirely by the supplier of the finished product. We recommend to follow NIAS guidelines; e.g. guidelines published by the Food Packaging Committee of the Italian Packaging Institute.

根据（EU）2011/10 第 19 条，进行 NIAS 风险评估的责任完全在于成品的供应商。我们建议遵循 NIAS 指南；例如，意大利包装协会食品包装委员会发布的指南。



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Note 注意

In all EU countries, the finished articles are required to meet the Overall Migration Limit (OML) requirements (10 mg/dm(sq) or 60 mg/kg food) and Specific Migration Limit (SML) requirements where applicable, as specified in EU Regulation No. 10/2011. Migration depends on several factors, as thickness of the article in contact with food (or with a proper food simulant), surface to volume ratio, conditions of use (contact time and temperature) and the type of food, as well. It is therefore responsibility of the producer of the final article to guarantee its compliance with food contact applications under actual or foreseeable conditions of use, and to check it on a regular basis.

在所有欧盟国家中，成品需符合总体迁移限定值（OML）的要求（10mg/dm(sq)或60mg/kg food）和10/2011号欧盟法规中适用的特定迁移限定值要求。迁移取决于多种因素，即食品接触物品（或适当的食品模拟物）的厚度、表面积与体积之比、使用条件（接触时间和温度）及食物类型。因此成品的生产者有责任保障其符合实际或可预测的使用条件下的食品接触应用，并定期进行检测。

Food contact compliance USA

美国的食品接触法规

US FDA CFR Code of Federal Regulations Title 21 (2017).

美国FDA CFR联邦法规第21章（2017）

Styrene Block Copolymers (SEBS, SEEPS, SEPS, SBS,..etc.) used shall be compliant with 21CFR 177.1810 and/or have a FDA Food Contact Notification (FCN) number.

所使用的**苯乙烯嵌段共聚物**（SEBS，SEEPS，SEPS，SBS等）应符合21CFR 177.1810和/或拥有FDA的食品接触材料通告（FCN）号。

Polyolefins used (PP, PE,...) shall be compliant with 21 CFR 177.1520 Olefin Polymers, whilst specific ethylene copolymers (EVA, EMA etc.) are referenced in other Chapter 177 sections.

使用的**聚烯烃**（PP，PE，...）应遵守21 CFR 177.1520对烯烃聚合物的规定，而特定的乙烯共聚物（EVA，EMA等）则参考177章节的其他内容。

Additives used, including paraffinic white oil, are referenced in other 21 CFR Chapters.

使用的添加剂包括凡士林白油可参考CFR第21章的其他内容。

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