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## Product Stewardship Bulletin (PSB) for Witcom and Cawiton grades intended to be used for food contact applications (May 2020)

### 用于食品接触应用领域的Witcom和Cawiton材料产品管理公告(2020年5月)

Witcom and Cawiton grades as produced by the Wittenburg Group and 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 Witcom and/or Cawiton grade issued. The “soft” elastomeric components of Witcom and/or Cawiton thermoplastic elastomer (TPE) materials may include TPE-S (Styrene Block Copolymers), thermoplastic olefins (TPE-O), 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.

Wittenburg集团生产用于食品接触应用领域的Witcom和Cawiton材料符合要求的法律法规。将在发布的Witcom和/或Cawiton材料产品数据表中对食品接触合规进行整体参照。Witcom和/或Cawiton热塑性弹性体(TPE)材料的“软”弹性体组分可能包含TPE-S(苯乙烯分段共聚体)、热塑性烯烃(TPE-O)、热塑性聚氨酯(TPU)、共聚酯弹性体(COPE)或聚醚嵌段酰胺(PEBA)，“硬”共混物组分可包含聚烯烃(PP, PE)、特种乙烯共聚物(EVA, EMA)、或Topas COC。链烷烃白油还可以作为填充油。

Hard engineering plastic materials include polyamides e.g. PA6, PA66, PPA, PA12, PA6.12, amorphous or semi-crystalline polyesters e.g. PC, PBT, PET(G), and blends thereof, special copolyesters, PLA and PLA/PHA blends, polyolefins e.g. LDPE, HDPE, PP homo-and copolymers e.g. PP-H, PP-C, aliphatic polyketones, ethylene copolymers e.g. EVA, EMA, EEA, styrenics e.g. PS, HIPS, ABS, SAN, and high temperature materials e.g. PEI, PES, PSU, PPSU, PPS, PAEK.

硬工程塑料材料包括聚酰胺，例如PA6，PA66，PPA，PA12，PA6.12，无定形或半结晶聚酯，例如PC，PBT，PET(G)及其混合物，特殊共聚酯，PLA和PLA/PHA混合物，聚烯烃如LDPE，HDPE，PP均聚物和共聚物，如PP-H，PP-C，脂肪族聚酮，乙烯共聚物，如EVA，EMA，EEA，苯乙烯如PS，HIPS，ABS，SAN和高温材料如PEI，PES，PSU，PPSU，PPS，PAEK。

### Raw material policy 原材料政策

All raw materials used in compounding of Witcom and 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 Wittenburg Group 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Witcom和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Wittenburg集团其产品成分、产品属性(生产工艺改变或原材料来源有变)和产品法规状况的变化。原材料生产地址改变时，无需通知。



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## 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/temperature of storage conditions 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、储存条件时间/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验。

**Commission Regulation (EU) 2011/10 (positive list)** as amended by (EU) 321/2011, (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014, (EU) 2015/174, (EU) 2016/1416, (EU) 2017/752, (EU) 2018/79, (EU) 2018/213, (EU) 2018/831, (EU) 2019/37 and (EU) 2019/1338 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. Wittenburg Group will gather all available supplier information on relevant migration restrictions (SML; QM) and Dual Use additives present and make that available on customer request, under confidentiality agreement, to support migration testing.

**欧委会法规(EU) 2011/10 (肯定列表)**根据(EU) 321/2011, (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014, (EU) 2015/174, (EU) 2016/1416, (EU) 2017/752, (EU) 2018/79, (EU) 2018/213, (EU) 2018/831, (EU) 2019/37 and (EU) 2019/1338针对与食品接触的塑料材料和物品进行了修订。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I中，其内容与塑料材料和食品接触物品相关。

Wittenburg集团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，并可以在签署保密协议的前提下按照客户的需求提供，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.

Wittenburg Group 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。Wittenburg集团声明，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。

### Note注意

In all EU countries, the finished articles are required to meet the Overall Migration Limit (OML) requirements (10 mg/dm<sup>2</sup> 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 the 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，要求成品符合欧盟法规10/2011号中规定的总迁移限量（OML）要求（10 mg/dm<sup>2</sup>或者60 mg/kg食物）和特定迁移限量（SML）的适用要求。迁移取决于几个因素，例如与食品（或者与适当的食物模拟物）接触的物品厚度，表面积与体积比，使用条件（接触时间和温度）以及食物类别。因此，最终产品的生产商有责任确保其在实际或者可预见使用条件下符合食品接触应用要求，并定期进行检查。



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## 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。

## Food contact compliance USA

### 美国的食品接触法规

#### US FDA CFR Code of Federal Regulations Title 21 (2019).

#### 美国FDA CFR联邦法规第21章 (2019)

**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。

**Thermoplastic polyurethane grades** (TPU) used shall be compliant with FDA, Title 21CFR 177.1680 and 177.2600.

所用的**热塑性聚氨酯**材料 (TPU) 应符合FDA，标题21CFR 177.1680和177.2600的要求。

**Thermoplastic copolyester elastomer grades** (COPE) used shall be compliant with FDA, Title 21CFR 177.2600 and/or 177.1590.

所用的**热塑性共聚酯弹性体**材料 (COPE) 应当符合FDA，标题21CFR 177.2600和/或177.1590的要求。



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**Polyolefins** used (PP, PE,...) and also **Cyclic Olefin Copolymer (COC)** shall be compliant with 21CFR 177.1520 Olefin Polymers.

所用的**聚烯烃** (PP, PE...) 以及**环状烯烃共聚物** (COC) 应当符合21CFR 177.1520烯烃聚合物。

**Polycarbonate (PC) resins** used shall be compliant with 21CFR 177.1580 Polycarbonate resins.

所用的**聚碳酸酯 (PC) 树脂**应符合21CFR 177.1580聚碳酸酯树脂。

**Polyester resins** used shall be compliant with 21CFR 177.1660 Poly (tetramethyleneterephthalate) (PBT); 21CFR 177.1630 Polyethylene phthalate polymers (PET(G)) or with specific Food Contact Notifications (FCN).

使用的**聚酯树脂**应符合21CFR 177.1660聚 (对苯二甲酸丁二醇酯) (PBT) ;

21CFR 177.1630聚邻苯二甲酸乙二酯聚合物 (PET (G)) 或特定的食品接触通知 (FCN) 。

**Polyamides resins** used shall be compliant with 21CFR 177.1500 nylon resins.

使用的**聚酰胺树脂**应符合21CFR 177.1500尼龙树脂的要求。

**Polystyrene (PS)** and **rubber-modified polystyrene (HIPS)** used shall be compliant with 21CFR 177.1640.

使用的**聚苯乙烯 (PS)** 和**橡胶改性的聚苯乙烯 (HIPS)** 应符合21CFR 177.1640。

**Acrylonitrile Butadiene Styrene (ABS) copolymers** used shall be compliant with 21CFR 177.1020.

使用的**丙烯腈丁二烯苯乙烯 (ABS) 共聚物**应符合21CFR 177.1020。

**Acrylonitrile Styrene (SAN) copolymers** used shall be compliant with 21CFR 177.1040.

使用的**丙烯腈苯乙烯 (SAN) 共聚物**应符合21CFR 177.1040。

**Ethylene Vinyl Acetate (EVA) copolymers** used shall be compliant with 21CFR 177.1350.

使用的**醋酸乙烯酯 (EVA) 共聚物**应符合21CFR 177.1350。

**Ethylene Methyl Acrylate (EMA) copolymers** used shall be compliant with 21CFR 177.1340, whilst

**Ethylene Ethyl Acrylate (EEA) copolymers** used will be compliant with 21CFR 177.1320.

使用的**乙烯丙烯酸甲酯 (EMA) 共聚物**应符合21CFR 177.1340, 而所使用的**乙烯丙烯酸乙酯 (EEA) 共聚物**应符合21CFR 177.1320。

**Polyetherimide (PEI) resins** used shall be compliant with 21CFR 177.1595.

所使用的**聚醚酰亚胺 (PEI) 树脂**应符合21CFR 177.1595。

**Polysulfone (PSU) resins** used shall be compliant with 21CFR 177.1655.

使用的**聚砜 (PSU) 树脂**应符合21CFR 177.1655。

**Polyether sulfone (PES) resins** used shall be compliant with 21CFR 177.2440.

使用的**聚醚砜 (PES) 树脂**应符合21CFR 177.2440。

**Polyaryletherketone (PAEK) resins** used shall be compliant with 21CFR 177.1556.

使用的**聚芳基醚酮 (PAEK) 树脂**应符合21CFR 177.1556。

**Polyphenylene sulfide (PPS) resins** used shall be compliant with 21CFR 177.2490.

使用的**聚苯硫醚 (PPS) 树脂**应符合21CFR 177.2490。

**Colorants** used shall generally be compliant with 21CFR 178.3297 Colorants for Polymers.

所用的**着色剂**通常应符合21CFR 178.3297聚合物着色剂的要求。

**Additives** used, including paraffinic white oil, are referenced in other 21 CFR Chapters and/or are Generally Recognized As Safe (GRAS) and/or have a FDA FCN.

所用的**添加剂**, 包括石蜡白油, 在其他21 CFR章节中提到和/或通常被公认为安全 (GRAS) 和/或具有FDA FCN。

### US FDA Food Types & Conditions of Use restrictions

#### 美国FDA食品类型和使用限制条件

Specific restrictions with regards to food types (I - IX), as identified in Table 1 in FDA, Title 21CFR 176.170 (c), and conditions of use (A - J), as listed in Table 2 in FDA, Title 21CFR 176.170 (c), can be applicable to the above stated components, and correspondingly on our Witcom and Cawiton products. These restrictions will be made available on customer request.



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对食品类型（I-IX）的特定限制如FDA标题21CFR 176.170（c）中表1所示，使用条件（A-J）如FDA标题21 CFR 176.170 (c)表2中所列，可适用于上述组件，并相应地适用于我们的Witcom和Cawiton产品。这些限制将根据客户要求提供。

We would like to point out that it is the responsibility of the end-use manufacturer to ensure that the final products/articles meet the extractive limitations for its intended use.

我们想指出的是最终产品制造商有责任确保最终产品/物品符合其预期用途的提取限制。

Disclaimer 免责声明

*We need to make clear that the responsibility for the use of the final products/articles (with respect to food contact regulations) rests entirely at the end-use manufacturer. He should ensure that his products comply with the migration and concentration requirements imposed and that it is produced under the right circumstances. By using any Technical Information contained herein, you agree that said technical information is given for convenience only, based on supplier information, and without any warranty or guarantee of any kind, and is accepted and used at your sole risk. As used in this paragraph, "Technical Information" includes any technical advice, recommendations, testing, or analysis, including, without limitation, information as it may relate to the selection of a product for a specific use and application.*

我们需要明确指出，最终产品/物品（与食品接触法规有关）的使用的责任完全有最终产品制造商承担。他应当确保其产品符合法规中的迁移和浓度要求，并在正确的条件下生产。使用任何此处提及的技术信息时，你方同意所述技术信息只是为方便起见，且皆基于供应商信息，不作任何保障，你方将自己接受并承担风险。在此段落的内容中，“技术信息”包括任何技术设备、建议、检测或分析，其中包括但不限于与用作特定用途的产品选择信息。

Product Stewardship & Regulatory Affairs Wittenburg Group

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