



WITTENBURG

Your partner in TPE, medical & food compounds

B.V. Rubberfabriek Wittenburg
Postbus 32 – 3870 CA Hoevelaken
Productieweg 12
3899 AK Zeewolde
The Netherlands
Tel.: +31 (0)36 2000300
Fax: +31 (0)36 2000301
Mail info@wittenburgbv.nl

Product Stewardship Bulletin (PSB) for Cawiton TPE grades intended to be used for food contact applications (August 2019)

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.

Raw material policy

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 Wittenburg 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.

Food contact compliance EU

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.

Commission Regulation (EU) 2011/10 (positive list) as amended by 321/2011/EU (restriction of use of BPA in plastic infant feeding bottles), 1282/2011/EU, 1183/2012/EU, 202/2014/EU, 174/2015/EU, 1416/2016/EU, 752/2017/EU, 79/2018/EU, 213/2018/EU, 831/2018/EU, 37/2019/EU and 1338/2019/EU 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 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.

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 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.

Not Intentionally Added Substances (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.

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



WITTENBURG

Your partner in TPE, medical & food compounds

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.

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.

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.

Note

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.

Food contact compliance USA

US FDA CFR Code of Federal Regulations Title 21 (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.

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.

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

Disclaimer

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.

We trust this information is conform your request and we remain,

Wittenburg B.V.
Productieweg 12
3899 AK Zeewolde
tel: +31 - 362000300 fax: +31-362000301

J.T. Scholtens

Product Stewardship & Regulatory Affairs, Wittenburg B.V.