



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

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.

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.

Raw material policy

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.

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/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.

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, (EU) 2019/1338 and (EU) 2020/1245** 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. Our Witcom and Cawiton grades may contain traces of metal elements listed in Annex II, which are present as impurities, originating from the sequence of processing steps at our down-stream users, and at our own manufacturing process.

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

G R O U P

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.

Note

In all EU countries, the finished articles are required to meet the Overall Migration Limit (OML) requirements (10 mg/dm² 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.

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 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.

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.

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

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

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

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

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).



WITTENBURG

G R O U P

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

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

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

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

Ethylene Vinyl Acetate (EVA) copolymers used shall be compliant with 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.

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

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

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

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

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

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

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.

US FDA Food Types & Conditions of Use restrictions

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.

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.

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.

Product Stewardship & Regulatory Affairs Wittenburg Group

Polypropylene PPH 10060

Content:

- Technical Data Sheet
- Regulatory Certificate
 - Statement of compliance for food contact applications
 - Statement on toys
 - Statement on Transmissible Bovine Spongiform Encephalopathy (BSE) and Genetically Modified Organisms (GMO)
 - Statement on inventories
 - Statement on Pharmacopoeia

For other Regulations, please consult our Product Stewardship Certificate available on this website. We have included in our Polypropylene Product Stewardship Certificate the conformity to a number of regulations whenever it could be certified for all our European polypropylene products.

In case you might need additional technical or regulatory information, please contact your sales representative.



Description

Polypropylene PPH 10060 is homopolymer with a Melt Flow Index of 35 g/10 min.

Polypropylene PPH 10060 is characterized by high fluidity and is particularly suitable for injection moulding applications. The material provides a good balance between stiffness and impact and allows reduced injection pressure, even for thin walled articles.

Characteristics

	Method	Unit	Typical Value
Rheological properties			
Melt Flow Index 230°C/2.16 kg	ISO 1133	g/10 min	35
Mechanical properties			
Tensile Strength at Yield	ISO 527-2	MPa	32
Elongation at Yield	ISO 527-2	%	9
Tensile modulus	ISO 527-2	MPa	1600
Flexural modulus	ISO 178	MPa	1500
Izod Impact Strength (notched) at 23°C	ISO 180	kJ/m ²	2.5
Charpy Impact Strength (notched) at 23°C	ISO 179	kJ/m ²	3
Hardness Rockwell - R-scale	ISO 2039-2		96
Thermal properties			
Melting Point	ISO 3146	°C	165
Vicat Softening Point	ISO 306	°C	
50N-50°C per hour			89
10N-50°C per hour			153
Heat Deflection Temperature	ISO 752	°C	
1.80 MPa - 120°C per hour			55
0.45 MPa - 120°C per hour			100
Other physical properties			
Density	ISO 1183	g/cm ³	0.905
Bulk Density	ISO 1183	g/cm ³	0.525

Safety and Product Stewardship

For safe use and handling, please refer to the Safety Data Sheet.

A Product Stewardship certificate giving the conformity to various regulations or statements on absence of certain chemicals is also available on our web site www.polypropylene.totalpetrochemicals.com

An Injection Moulding troubleshooting guide is available upon request.

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Feluy, March 12, 2009

POLYPROPYLENE PPH 10060

STATEMENT OF COMPLIANCE FOR FOOD CONTACT APPLICATIONS :

In the EUROPEAN UNION

We confirm that the above-mentioned Product fulfils the harmonised requirements on materials used for articles or components of articles intended to come into contact with food as described in the European Directive 2002/72/EC amended by Directives 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and its transposition into national laws as incorporated in the following contact regulations:

in Belgium :

- Arrêté Royal du 03/07/2005 concernant les matériaux et objets destinés à entrer en contact avec les denrées alimentaires (Moniteur Belge du 29/07/2005).
- Arrêté Royal du 05/07/2006 (Moniteur Belge du 07/09/2006) modifiant l'Arrêté Royal du 3/07/2005.

in France :

- Décret Ministériel n° 73-138 du 12/02/73 et n° 2007-766 du 10/05/2007 ainsi que les lettres circulaires de la Répression des Fraudes et contrôle de la qualité (Recueil de textes: brochure n° 1227 "Matériaux au contact des aliments et denrées destinées à l'alimentation humaine" - dernière édition : 15/07/2002);
- Instruction relative à l'emploi d'additifs dans les matières plastiques au contact des denrées alimentaires (Bulletin Officiel de la concurrence, de la consommation et de la répression des fraudes du 11/08/93);
- Arrêté du 19/10/2006 modifiant l'arrêté du 02/01/2003 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact avec les denrées, produits et boissons alimentaires.

in Germany :

- Gesundheitliche Beurteilung von Kunststoffen im Rahmen des Lebensmittel- und Bedarfsgegenständegesetzes (BfR): Empfehlung VII: Polypropylen Stand 01.06.2007 - 210 Mitteilung - B. Gesundh. Bl. 50 (2007) 1470,
- Bedarfsgegenstandsverordnung vom 10. April 1992 (BGBl.I.S.866) und Änderungen vom 11. April 1993 (BGBl.I.S.775), vom 17. April 1997 (BGBl.I.S.796), vom 21. Dezember 2000 (BGBl. I. S.1886), vom 7. April 2003 (BGBl.I.S.486) und vom 6. September 2005 (BGBl.I.S.2618).

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CERTIFICATE N° 33474

Feluy, March 12, 2009

POLYPROPYLENE PPH 10060

in Italy :

- Decreto Ministeriale 21/03/1973 (G.U. n° 104 - 20/4/1973) Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale as amended by Decree of the Ministry of Health N°411 of 1/12/2000 (G.U. N°11-15/01/2001)
- Decreto Ministeriale 26/04/1993, n°220 (G.U. n° 162 - 13/7/1993) Regolamento recante aggiornamento del decreto ministeriale 21/03/1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari e con sostanze d'uso personale as updated up to D.M.H n° 82 of 18/04/2007 (G.U. N°151 - 02/07/2007).

in the Netherlands :

- Verpakkingen- en gebruiksartikelenbesluit (Warenwet) - Deel A, Hoofdstuk 1 : Kunststoffen, VGB, 27e suppl., December 2008.

in Spain :

- Orden SCO/ 983/ 2003 de 15 de abril (B.O.E. n° 99 de 25/04/2003) .
- Resoluciones del Ministerio de Sanidad de 04.11.1982 (B.O.E. n° 282 de 24.11.1982).
- Orden del Ministerio de Sanidad de 03.07.1985 (B.O.E. n° 166 de 12.07.1985).
- Real Decreto 2207/1994 de 16/11/1994 as updated to R.D. 442/2001.
- Real Decreto 118/2003 de 31/01/2003 as updated to R.D. 866/2008.

in the United kingdom :

- The Plastic Materials and Articles in Contact with Food Regulations - 2008
- England: Statutory Instruments 2008/916
- Northern Ireland: Statutory Rules 2008/167
- Scotland: Statutory Instruments 2008/127
- Wales: Statutory Instruments 2008/1237 (W.124)

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Feluy, March 12, 2009

POLYPROPYLENE PPH 10060

Conditions:

- Regarding overall migration:

According to the Directives 82/711/EEC (and its amendments 93/8/EEC and 97/48/EEC), 85/572/EEC and 2002/72/EC, the overall migration limit, for which a maximum value of 10 mg/dm² or 60 mg/kg is set (Directive 2002/72/EC, article 2) , has to be controlled on the finished articles intended to come into contact with foodstuffs; consequently it is the responsibility of the end-user of the above-mentioned Product.

Specific Migration Limit(s):

Restriction for Monomer ^{a)}: none.

Restriction for Additive(s) ^{b)}: none.

European Directive 2004/19/EC and its transposition into national laws.

We inform you that we do not use food additives as authorized by and subject to a restriction in the European Directive 89/107/EC and/or flavorings as authorized by the European Directive 88/388/EC during the manufacturing of the above-mentioned Product. However, since we do not perform specific tests to verify the potential presence of any of these food additives, we cannot guarantee that there is no trace amount of some of these substances, as impurity or otherwise, in the above-mentioned Product.

REGULATION 1935/2004/EC

We hereby confirm that the above-mentioned Product, when used under normal or foreseeable conditions of use, meets the relevant requirements laid down in Regulation 1935/2004/EC.

REGULATION 2023/2006/EC (GMP)

We inform you that the production of the above-mentioned Product is systematically reviewed with regards to good manufacturing practice (GMP) using our ISO 9001 System, and following the Plastics Europe guideline specifically dedicated to GMP.

Therefore we can state that the above-mentioned Product meets the relevant requirements laid down in Regulation 2023/2006/EC.

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POLYPROPYLENE PPH 10060

in the UNITED STATES OF AMERICA :

- Code of Federal Regulations Food and Drugs Title 21 - 2008 - §177.1520 : Olefins Polymers;
For PPH : (c) (item 1.1), §176.170(c), categories I through IX of Table 1, under conditions of use A through H of Table 2 .

GENERAL USE CONDITIONS :

it pertains to end-users of materials intended to come into contact with food, to ensure that the material does not bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristics which render it unfit.

STATEMENT ON TOYS - EUROPEAN STANDARD EN 71- 3.1994 and EN 71- 9.2005 :

We hereby confirm that the above-mentioned Product meets the requirements of European Standard EN 71-3 1994 its amendment EN 71- 3/ A1 2000 corrigendum AC: 2002 entitled "Safety of Toys - Part 3 : Migration of certain elements" and EN 71-9, September 2005 "Organic chemical compounds- requirements".

The above-mentioned Product meets this standard because every time analyses were performed on this product, results were below the prescribed limits.

STATEMENT ON NO COMPLIANCE WITH EUROPEAN PHARMACOPOEIA :

We **DO NOT** certify that the above-mentioned product would comply with the European pharmacopoeia.

STATEMENT ON NO COMPLIANCE WITH UNITED STATES PHARMACOPOEIA :

The above-mentioned product is **NOT** in compliance with the US pharmacopoeia because we **DID NOT** perform the required tests.

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Feluy, March 12, 2009

POLYPROPYLENE PPH 10060

STATEMENT ON TRANSMISSIBLE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) :

We hereby confirm that we did receive an indication from our suppliers of additives used in our product mentioning the absence of any substances which are of animal origin.
Based on the above, we are confident that our product are free of SRM (Specified Risk Materials).

STATEMENT ON GENETICALLY MODIFIED ORGANISMS (GMO).

We hereby confirm that we did receive an indication from our suppliers of additives ^{b)} used in the above-mentioned Product mentioning the absence of any Genetically Modified Organisms (GMO).

STATEMENT ON INVENTORIES:

We declare that the monomers and, if present, the additives ^{b)} of the above-mentioned Product are listed or exempted from listing on:
AICS, DSL, ECL, EINECS AND/OR ELINCS, ENCS, PICCS and TSCA.

NOTE :

- a) Monomer as defined in the EC Directive 2002/72/EC up to 2008/39/EC.
- b) Additive as defined in the EC Directive 2002/72/EC up to 2008/39/EC.

DISCLAIMER :

Our certificate does not cover:

- any modification of the the above-mentioned Product by any addition of any other product or Ingredient to it;
- any prejudicial modification of the above-mentioned Product resulting from a processing of it;
- an inadequate use and/or storage of the above-mentioned Product and/or of the finished articles.

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Page 6/6

CERTIFICATE N° 33474

Feluy, March 12, 2009

POLYPROPYLENE PPH 10060

The present certificate is valid until end 2009. Upon the expiration of this certificate, we can issue a new one at your request. In case of change during this period a new certificate will be issued automatically; kindly forward it to any recipient of the present certificate.

TOTAL PETROCHEMICALS RESEARCH FELUY

C. RAIMOND
Regulatory Affairs

F. WYLIN
Regulatory Affairs, Manager

Issued by an electronic system

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REACH
**CUSTOMER
INFORMATION**

SUBJECT: REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), together with the Substances of Very High Concern (SVHC) listed on the REACH Candidate List as published on the European Chemicals Agency (“ECHA”) website and updated until 17 January 2022.

NV Bekaert SA (“Bekaert”) wishes to assure you that it takes the changes associated with the REACH Regulation seriously. Bekaert is closely following the evolution of the REACH regulation and related guidance documents as published by ECHA.

All Wire products (including Industrial Steel and Steelcord wire), produced in:

- Europe: BKZW – BKTX – BKAA – BKSA – BKBU – BKSR – BFUA – BKIZ – BKKT – BKSL – BKHL – BBUK – BKPE – BKBO – BKLP – BHTR
- North America: BKRG – BKVB – BKOR – BKRO – BWB
- Japan: BTMF
- China: BCSC – BJWP – BBSC – BJSC – BQWP – CBSC – BAP – BSAC – BSTC – BAMT
- Indonesia: PTBI – BSWK
- India: BIPL – BMWI

(including packaging) are articles without substances intended to be released, based on the *Guidance on requirements for substances in articles* dated June 2017, as published by ECHA.

In respect of the aforementioned products, Bekaert’s role under the applicable REACH regulation is mainly (1) the downstream use of substances, mixtures and articles, and (2) the production of articles.


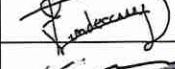
As a result, Bekaert does not supply articles requiring submission of information in the SCIP – database which is established under the revised Waste Framework Directive 2008/98/EC.

Bekaert can confirm that it does not supply products with SVHC in concentrations higher than 0.1% weight by weight (w/w) included in the REACH Candidate List, nor included in the REACH Authorization List (Annex XIV). Bekaert monitors the REACH restriction list and confirms compliance with the restriction list as long as the end user is using our articles for the intended and legally approved uses (e.g. nickel-coated wire may not be used in articles intended to come into direct and prolonged contact with the skin).

Disclaimer:

To the best of our knowledge, the information contained in this Customer Information is accurate and reliable on presently available resources. However, neither NV Bekaert SA nor any of its affiliated companies assumes any responsibility or liability whatsoever for the accuracy or completeness of the information contained herein.

This Customer Information shall not constitute a guarantee for any specific product features. Final determination of suitability of this material is the sole responsibility of the user. All materials may present unknown hazards and should be used and handled with caution and following reasonable safety procedures. Consequently, the buyer assumes all risks in connection with the use and handling of this material.

Approved by:	Date:	Signature:
Silvie Coutuer – Global QA & SQM Manager	2022/02/08	
Rikie Vandecruys – VP SH&E	2022/02/10	
Yves Kerstens – Divisional CEO Specialty Business & Chief Operations Officer	2022/04/16	
Arnaud Lesschaeve – Divisional CEO Rubber Reinforcement	2022/02/18	
Stijn Vanneste – Divisional CEO Steel Wire Solutions	2022/02/21	
Curd Vandekerckhove – Divisional CEO BBRG	2022/02/21	