

Fecha de declaración: 1 Junio de 2023

Distribuidor: Hilados Biete, S.L.

Contacto: Email: ressol@hiladosbiete.com Telefono: (+34) 96 533 07 47

Material: PP (Polipropileno).

Color: Azul, Rojo, Verde, Amarillo y Blanco.

Hilados Biete, S.L. declara que ha recibido de sus proveedores de materiales una declaración confirmando que los siguientes productos:
05716, 05731, 05707, 05708, 05709, 05710, 05711, 05726, 05712, 05713, 05714, 05715, 05718, 05705, 05724, 05725.

Cumplen con los siguientes reglamentos:

- Reglamento (CE) N° 1935/2004.
- Reglamento (CE) N° 2023/2006.
- Reglamento (CE) 10/2011 (Sustancias autorizadas para la fabricación de materiales y objetos plásticos en contacto con alimentos.)

Uso previsto del producto:

Tipo de alimento para contacto: Todos los tipos de alimentos.

Uso repetitivo o intermitente.

Es importante limpiar, desinfectar y esterilizar el equipo después de su uso. Desinfectables en autoclave hasta 140°C.

Tiempo y temperatura:

Cualquier uso a largo plazo a temperatura ambiente o por debajo, incluyendo hasta 60 ° C durante un máximo de 2 horas.

La temperatura máxima a corto plazo entre -30°C y + 80°C.

La temperatura máxima a largo plazo entre +5°C y + 40°C.



The polyolefin base resins used are compliant with FDA requirements contained in 21 CFR 177.1520. Also the additives used are FDA cleared as GRAS (generally Recognised As Safe) or under specific FDA citations.

All colorants used are listed in-line with FDA requirement 21. CFR 178.3297 'Colorants for Polymers'

EU Regulation No.1935/2004

Regarding materials and articles which, in their finished state, are intended for, or expected to come into direct contact with food. All product codes as listed above are covered by this regulation and are approved to be labelled as such or by using the 'Glass & Fork' symbol as illustrated below.



EU Regulation No.10/2011 with amendments

The material was tested in accordance with the requirements of the Plastic Materials and Articles in Contact with Food Commission Regulation (EU) No. 10/2011 following Methods BSEN 1186:2002.

The Regulations require that no plastic material shall be capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit.

For the material the appropriate limit is 10 mg/dm².

We confirm that the material has been formulated and manufactured in accordance with the compositional requirements of the following food contact recommendations or regulations:

EU

Commission Regulation (EU) No. 10/2011 of January 14, 2011, effectively replacing EC Commission Directive 2002/72/EC of August 6, 2002, as amended. This material contains no monomers which are regulated with a specific migration limit. This material does not contain intentionally incorporated additives which are regulated with a specific migration limit. This material contains one or more intentionally added dual use additives which are subject to disclosure of adequate information as described in Annex VIa of Directive 2007/19/EC. The identity of this/these substance(s) can be disclosed for testing purposes upon special request and under maintaining secrecy. This material has been manufactured in accordance with the relevant requirements of Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Good working practices:

All procedures regarding the manufacturing of these products, including raw material supply, storage, processing, quality control, testing and packing are in accordance, adhere to and are compliant with European Directive EU 2023/2006.

In respect of European Commission regulation# 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. This particular regulation refers specifically to EC regulation

1935/2004/EC in terms of materials. This is to confirm that the ingredients used to manufacture the products listed below and the way these materials are handled, the processes they are put through are all subject to the Quality Assurance system (ISO9001 :2008) as approved by ISOQAR. As such this means we, and the products listed below meet the European Commission regulation # 2023/2006.

This is to confirm that this master batch is formulated and manufactured using materials of a synthetic origin using good manufacturing practices that meet European Commission regulation # 2023/2006.

There are no ingredients in the formulation of our hygiene PP material that is of animal origin. As such, this material should not pass on any Animal derived disease like BSE (Bovine Spongiform Encephalopathy) or other TSE (Transmissible Spongiform Encephalopathy).

We have to inform you that our hygiene material contains traces (1-10 ppm) of a phthalate, originated from the used catalyst system. These traces fully comply with the EC Directives 2005/84/EC and Commission Regulation (EU) 10/2011 and amendments.

We can also inform you, that this material is not subject to Annex XIV (Authorisation) of Regulation (EC) No 1907/2006 (also known as REACH), since the possible traces phthalate present in our material are either regarded as an impurity or are far below the threshold of 0.1% (1000 ppm) as mentioned in Article 56(6) (b) of REACH (see also our REACH declaration).

We confirm that no Allergens that are recognised by the EU FIC and FDA are used in the production of our products.

We guarantee that if any facilities contain any allergens that are recognised by the EU FIC and FDA, said allergens must be identified as present in the form of an allergen survey

Biphenyl Declaration:

According to the recipe in the production of SABIC® PP 83MF10 00900 the following substances as such are not intentionally used or added: the heavy metals cadmium, lead, chromium (VI) and mercury (brominated) flame retardants polybrominated biphenyls (PBB's) and -diphenyl ethers (PBDE's)

It is therefore our opinion that:

- Since this material does not contain a brominated flame retardant, this material is therefore not subject to the selective waste requirements of Annex II of the EC Council Directive 2002/96/EC on the waste of electrical and electronic equipment (WEEE).
 - This material complies with the requirements for 'heavy metals' according to the EC Council Directive 94/62/EC (and amendments) and 2000/53/EC (and amendments)
 - This material complies with the requirements for polybrominated biphenyls (PBB's) and - diphenyl ethers (PBDE's), such as they are regulated in EC Council Directive 2002/95/EC on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS).
 - This material complies with the requirements for octa- and pentabromodiphenylether according to EC Council Directive 2003/11/EC on the restriction on the marketing and use of certain dangerous substances and preparations (octabromodiphenylether and pentabromodiphenylether).
- The absence has not been checked by tests.

Bisphenol A

The material of these products is not intentionally manufactured or formulated with 4,4'-Bisphenol A (BPA), CAS # 80-05-7, EC # 201-245-8 and is compliant with (EU) 2018/2013.

Polymers made from Bisphenol-A monomer may be processed by our vendors company facilities.

Specifications of use:**Type or types of food with which it is intended to be put in contact;**

All types of food

Type of intended use of product;

Repetitive, intermittent use

Time and temperature of treatment and storage in contact with food.

Any long term treatment at room temperature or below, including up to 60°C for up to 2 hours.

Maximum short term operating temperature between -30°C to +80°C.

Optimal long term operating temperature between +5°C to +40°C.

Ratio of food contact surface area to volume used to establish the compliance of the product.

2 dm²/1 dl

All migration testing has been carried out by a UKAS accredited testing laboratory.



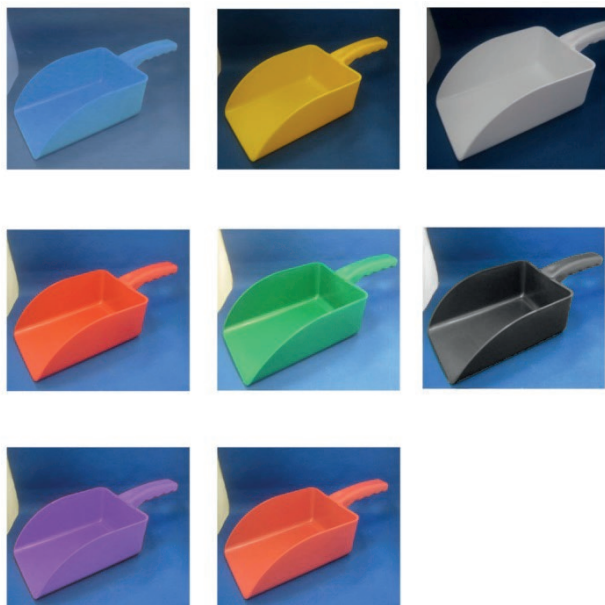
Overall migration test results

Simulant	Conditions	Migration (mg/dm ²)	OML (mg/dm ²)
Olive Oil	4 hours at 20°C	<3	10
95% Ethanol	24 hours at 40°C	<1	10
Iso-octane	4 hours at 20°C	<3	10
3% Acetic Acid	24 hours at 20°C	<2	10

Summary of results

The migration from the material was less than the maximum permitted by the Regulations and complies with the EU Regulation No. 10/2011 with amendments.

Photos of samples



Declaration of metals

Stainless Steel grade 304 is used for all metal components or additives and is compliant with EU and FDA regulations for direct contact with food suitability.

Specific Migration of Metals Testing

Method:

Sample preparation in 3% acetic acid (w/v) in aqueous solution at 70°C for 2 hours with reference to EN 13130-12004; followed by analysis using Inductively Coupled Argon Plasma Spectrometry (ICP)

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Specific Migration of Barium	NO	0.25	1
Specific Migration of Cobalt	NO	0.03	0.05
Specific Migration of Cooper	NO	0.25	5
Specific Migration of Iron	NO	0.25	48
Specific Migration of Lithium	NO	0.5	0.6
Specific Migration of Manganese	NO	0.25	0.6
Specific Migration of Zinc	NO	0.5	25
Comment	PASS	-	-

*** END OF REPORT ***