

8700-0417 Universal hose tubing connector, PP
8701-xxxx Connector straight, PP
8705-xxxx T-connector, PP
8706-xxxx Y-connector, PP
8707-xxxx Angled connector, PP
8708-xxxx Four-way connector, PP

Declaration of Compliance

Food regulatory assessment

Compliance with General Food Contact Legislation

Bürkle GmbH confirms that the products listed above are in compliance with the applicable requirements of the Regulation (EU) No. 1935/2004 and Regulation (EU) No. 10/2011 as amended in the current version.

We hereby declare that, in the manufacture of the products, it follows the good manufacturing practice requirements according to (EC) No. 2023/2006.

OML - overall migration limit

The overall migration limit is set at 10 mg/dm² contact surface according to Article 12 of the European Plastics Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 2016/1416). The analytical tolerance of the method is ± 2 mg/dm².

The products are in compliance with the overall migration limit in contact with all kinds of food for any long term storage at room temperature and below, including hot filling and heating up e.g. to 70 °C for up to 2 hours or to 100 °C for up to 15 minutes.

The determination of the overall migration in 95 % ethanol is at least as severe as the determination of the overall migration into olive oil and can be used as an alternative to the overall migration test in olive oil according to Annex V, Chapter 3, Section 3.4 of Regulation (EU) No 10/2011.

SML - specific migration limit

The specific migration limit of octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate is set at 6 mg/kg and of 9,9-bis (methoxymethyl)fluorene at 0.05 mg/kg food(simulant) according to Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 2016/1416).

Based on the solubility of the analytes, the fatty food simulants represent the more severe simulants compared to aqueous simulants.

The products are in compliance with the specific migration limits of octadecyl-3-(3, 5-di-tert-butyl-4-hydroxyphenyl) propionate and 9, 9-bis (methoxy-methyl)fluorene in contact with all kinds of food for any long term storage at room temperature and below, including hot filling and heating up e.g. to 70 °c for up to 2 hours or to 100 °C for up to 15 minutes.

FDA

For polypropylene described in 21 CFR § 177 .1520 (a) (1), the limit for the maximum extractable fraction in n-hexane is set at 6.4 % at reflux temperature and the limit for the maximum soluble fraction in xylene is set at 9.8 % at 25 °C according to 21 CFR § 177.1520 (c) 1.1.

The investigated polypropylene material is in compliance with the limit for the maximum extractable fraction in n-hexane as well as with the limit for the maximum soluble fraction in xylene according to the requirements of 21 CFR § 177.1520(c) 1.1.

Dual Use Additives

This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC:
E 470a Calcium salts of fatty acids

Our supplier of the raw material confirms the following:

BSE / TSE

Tallow derived additives may be used in the manufacture of the raw material. Tallow derived materials used in the raw material fulfill the requirements laid down in the Regulations 1069/2009/EC, 142/2011/EC and the "Note for Guidance EMEA/410/01, rev. 3".

Genetically Modified Organisms (GMO)

Additives derived from Genetically Modified Organisms (GMO's) are not intentionally used in the formulation of the raw material.

Latex

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for the raw material.

Allergen - Food Allergen European Regulation 1169/2011

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of the raw material. However, this product has not been tested for these substances.

Metals Content - EU Packaging and Packaging Waste

Based on the available documentation from raw materials suppliers of PP, this product complies with the directive 94/62/EC and its following amendments concerning the defined limit(s) of heavy metals.

Metals Content - US CONEG

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

Phthalates

Polyolefins do not require the use of plasticizers (such as phthalates) to make them soft and flexible. The raw material supplier does not add phthalates to its polyolefin products as plasticizers. However, traces of phthalates may be present in some products as impurities from the catalytic system.

Other Chemicals

The chemical materials listed below are not intentionally used in the manufacture or the formulation of the raw material. However, this product has not been tested for these chemical materials.

- Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1

The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 2284-08.

24. April 2019



Bürkle GmbH, Bad Bellingen,
Martin Saint-Denis, Managing Director

