

5379-00xx scoop / spatula / spoon / funnel, LaboPlast, Bio, misc. sizes
5379-10xx scoop / spatula / spoon, / funnel SteriPlast, Bio, misc. sizes

Declaration of Compliance

Food regulatory assessment - European Union

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.

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 limits

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 202/2014). The analytical tolerance of the method is ± 2 mg/dm².

The investigated samples are in compliance with the overall migration limit **for all types of food for any long term storage at room temperature and below, including hot fill and high temperature applications up to 121 °C.**

Conformity has been established by:

Determination of the overall migration (contact area/volume: 0.8 dm²/80 ml; testing period: 26.08. - 04.09.2014). The analyses were carried out on a representative sample (unirradiated) and are transferable to all other above listed 5379 series samplers.

SML - specific migration limit

In the investigated sample di-iso butylphthalate (DiBP) was quantified to be 100 µg/kg material. Assuming a total transfer (worst case) and applying an area weight of 9.1 g/dm² and a surface-volume ratio of 6 dm²/kg (according to EU-cube model) this corresponds to a theoretical concentration in the food of 5.5 µg/kg.

Di-iso butylphthalate (DiBP) is not listed in the European Plastics Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 202/2014) and therefore is not authorized as additive in plastics for food contact applications. However, di-iso butylphthalate (DiBP) may be used as an aid to polymerisation (e.g. of the catalyst system) according to national law.

According to the evaluation of DiBP in paper and cardboards by BfR² (German Federal Institute for Risk Assessment), DiBP can be evaluated by the readacross approach from DnBP, i.e. migration as sum of DiBP and DnBP shall be below 0.3 mg/kg food (simulant) (300 µg/kg).

Other phthalates and DEHA were not detectable in the sample material at the respective detection limits.

In conclusion, regarding the migration of the investigated phthalates and DEHA, the investigated sample "BIO-PE High Density Polyethylene" is in compliance with the general safety requirements of Article 3 of the European Framework Regulation 1935/2004 **in contact with all types of food and all contact conditions**.

Conformity has been established by:

Determination of phthalates and DEHA (testing period: 29.08. - 10.09.2014). The analyses were carried out on a representative sample (unirradiated) and are transferable to all other above listed 5379 series samplers.

Note on dual use substances

The raw material used may contain substances that are also approved for use as food additives:

- E 171: titanium dioxide (FCM No. 610)
- E 570: stearic acid and derivatives (FCM No. 106)

The information on dual use substances is provided by our raw material supplier. It seems very unlikely that a food additive used as a plastic additive will compromise the compliance with the regulatory threshold for this additive in the food product.

A functional barrier made from plastic is not used in the above mentioned products.

The user has to convince himself of the suitability of the product for the intended filling material which goes beyond the requirements of the directives.

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 002284-QM15.

06. July 2023



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



²Di-isobutylphthalate in food-contact paper and board - Minutes of the meeting of the working group "Paper and board" on 5 July 2007 at Bundesinstitut für Risikobewertung (BfR) Online available: http://www.bfr.bund.de/cm/230/di_isobutylphthalate_in_food_contact_paper_and_board.pdf