

5303-2xxx Control seal close-it food & pharma
5303-3xxx Control seal close-it food & pharma

Food Contact Statement

Herewith we confirm that the aggressive nature of the adhesive provides excellent performance on rough or difficult substrates such as rubber goods, shoes, rugs and carpets, as well as on packaging materials like cardboard, wood, fibre drums and plastic containers (e.g. HDPE and Polypropylene drums).

Face material

Categories of Food Evaluated and for which Lawfulness Has Been Confirmed:

- Dry Foodstuffs
- Fatty Foodstuffs

Compliance with following Regulations:

- EU Framework Regulation – (EC) No 1935/2004
- EU GMP Regulation – (EC) No 2023/2006
- 21 CFR 176.180 and 176.170 (paper)
- 21 CFR 172.878, 178.3620, 178.3910 (aluminium foil)

Adhesive

Categories of Food Evaluated and for which Lawfulness Has Been Confirmed:

- Dry, non-fatty Foodstuffs
- Moist Foodstuffs

Compliance with following Regulations:

- EU Framework Regulation – (EC) No 1935/2004
- EU Plastics Regulation – (EC) No 10/2011
- EU GMP Regulation – (EC) No 2023/2006
- 21 CFR 175.105 (dry food only or in combination with functional barrier)

Determination of the Overall Migration from the Adhesive

The determination was carried out according to EU Regulation (EU) No. 10/2011 following the standard EN 1186.

Testing conditions:

Test simulant:	ethanol 10 % (v/v)	ethanol 20% (v/v)	Tenax
Conditions:	24 hours at 40°C	10 days at 20°C	10 days at 20°C
Testing procedure:	one-sided contact (adhesive side)	EN 1186	EN 1186

The Overall Migration Limit does not exceed the threshold limit of 10 mg/dm².
The ratio of food contact surface area to volume is 6 dm²/kg.

Specific Migration Limits (SMLs):

The following substances are either listed in Reg. 10/2011/EU, or in EU Member State legislation or have been risk assessed and comply with Article 3.1 a) of Reg. 1935/2004/EU:

FCM	Substance Name	SML (mg/kg)
144	Isoprene	0.01
147	Acrylic Acid	T=6 (gr. restrict. 22)
150	Methacrylic Acid	T=6 (gr. restrict. 23)
165	Phtalic Acid	ND
223	Butadiene	0.01
316	Phthalic Acid, Diallyl Ester	ND
384	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tertbutylanilino)1,3,5-triazine	30
433	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate acrylamide	6
608	4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl)ditridecylphosphite	6
756	2,4-bis(octylmethyl)-6-methylphenol	5
765	2,4-dimethyl-6-(1-methylpentadecyl)phenol	1

Note with regard to SML substances listed in the table above: Two substances were not disclosed to us due to confidentiality from our supplier. They were assessed by our third party lab and are below the SML. These are not listed in the above SML list. Additional note with regard to SML substances not listed in the table above: Substances without a specific migration limit are not listed in the SML list.

Dual-Use Additives:

E-No.	Additive Name
E432-436	Polysorbates
E551	Silicon dioxide
E553b	Talc

NIAS

The adhesive may be considered safe for the intended use in keeping with Article 3 of the Framework Regulation (EC) No. 1935/2004 provided the safety of the low molecular weight oligomers present in the final food-contact article is further assessed. More specifically, a risk assessment should be conducted to assess the safety of all Non-Intentionally Added Substances (NIAS), including oligomers, present in the final food-contact article made with this adhesive. We did not further risk assess oligomers that may be present in this adhesive as this assessment would be of no, or quite limited, use given the further processing to produce the final article with this adhesive that will inevitably alter the oligomer profile in the final article. This risk assessment should be conducted in accordance with internationally recognized scientific principles on risk assessment (for example, risk assessment procedures referred to in Article 19 of the Plastics Regulation (EU) No 10/2011). It is ultimately the responsibility of the end-user of the final food-contact article to also (i) ascertain compliance with the overall migration limit (OML) as well as specific migration limits (SMLs) (where applicable), and (ii) confirm compliance with Article 3.1(c) of the Framework Regulation prohibiting the alteration of the organoleptic characteristics of the food.

ZERTIFIKAT CERTIFICATE

Pumpen | Probenehmer | Laborbedarf
für Labor, Industrie und Wissenschaft

Pumps | Sampling | Plastic Labware
for Laboratory, Industry, Science



Bisphenol A

The articles mentioned above are BPA-free.

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.

22. December 2022

A handwritten signature in blue ink, appearing to read "M. Saint-Denis".

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

