

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:

- Indirect contact with dry foodstuffs. Paper layer can stand direct food contact

Compliance with following Regulations:

- EU Framework Regulation – (EC) No 1935/2004
- EU GMP Regulation – (EC) No 2023/2006

Manufactured with components listed on, or compliant with, one of the following regulations:

- EU Plastics Regulation - (EU) 10/2011 with amendments
- 21 CFR § 176.180, 176.170 paper
- 21 CFR § 172.878, 178.3620, 178.3910 aluminium foil
- 21 CFR § 175.105 adhesive
- BfR Recommendation XXXVI

Adhesive

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

- Dry Foodstuffs
- Moist Foodstuffs
- Non-fatty Foodstuffs

Compliance with following Regulations:

- EU Framework Regulation – (EC) No 1935/2004
- EU Plastics Regulation – (EC) No 10/2011 with amendments
- EU GMP Regulation – (EC) No 2023/2006

Determination of the Overall Migration from the Adhesive

The determination was carried out according to EU regulation (EU) 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 40°C
Testing procedure:	one-sided contact (adhesive side)	EN 1186	EN 1186

The Overall Migration Limit does not exceed the threshold limit of 10.00 mg/dm². The ratio of food contact surface area to volume is 6 dm²/kg.

This allows for any long term storage at room temperature and below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Specific Migration Limits (SMLs):

FCM	Substance Name	SML (mk/kg)
144	Isoprene	0.01
223	Butadiene	0.01
384	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tertbutylanilino)1,3,5-triazine	30
608	4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditride cylyphosphite	6
150	Methylacrylic acid	6
147	Acrylic acid	6
165	Phthalic acid	0.01
316	Phthalic acid, diallyl ester	0.01
433	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6
756	2,4-bis(octylmethyl)-6-methylphenol	5
765	2,4-dimethyl-6-(1-methylpentadecyl)phenol	1

Dual-Use Additives

E number	Name of additive
E 553b	Talc
E 551	Silicon dioxide
E 432 - 436	Polysorbates

General

The user is responsible for the examination of the suitability of the packaging both for the planned filling good/foodstuff and kind of application.

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.

10. April 2024



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

