

2348-00xx Packaging bags with closure, LDPE

Declaration of conformity

laying down the rules on the packaging of foodstuffs

Our supplier hereby confirms that the above-mentioned products, which are used "for the packaging of foodstuffs", are suitable for this purpose under food law.

The products comply with the requirements of the following legal regulations, including all amendments and in the version valid at the time this declaration is issued:

- 1) Regulation EC No 1935/2004, dated 27. October 2004 on materials intended to come into contact with food
 - 1.1) Regulation EC No 2023/2006, dated 22. December 2009 (Good Manufacturing Practice) on good manufacturing practice for materials and articles intended to come into contact with food
- 2) Regulation EU 10/2011 (previously 82/711 EEC), amendments and correction, dated 28. April 2017 on Plastic food contact materials and articles
- 3) Consumer Goods Ordinance , dated 23. September 2009
- 4) Council Directive 82/711 EEC on migration assessment from materials intended to come into contact with food
- 5) Food and Feed Code (LFGB), dated 01. September 2005
- 6) Recommendations III, IX and X on food contact materials of BfR (Federal Institute for Risk Assessment)
- 7) Council of Europe Resolution AP(89) 1 - Purity requirements for the use of Colourants in plastics intended to come into contact with foodstuffs
- 8) FDA 21 CFR 177.1500 (b) 4.2, 177.1395, 175.105 § (c)(5), 177.1520 (c) 2.1,2.2, 3.1 a, 3.2a, 178.2010, 175.300, 175.320 and FDA 21 CFR 178.2010 (Federal Code of Registration/ Plastics in direct contact with food)
- 9) Packaging Directive 94/62/EC on Optimum packaging while avoiding the superfluous

1.1 Description of application (according to customer specification - if available)

Food	Treatment with food contact		Storage with food contact		Ratio contact area to filling quantity (dm ² /kg ¹)
	°C	d/h	°C	d/h	
dry			5- 25		
aqueous			5- 25		6.0
acid			5- 25		6.0
alcoholic			5- 25		
milk product			5- 25		
fatty			5- 25		6.0

1)the film composite is suitable for aqueous, acidic, fatty and dry²) foods

2)according to the Additives Framework Regulation, Annex 2, "Basic rules for determining migration", para. 4b

2.0 Migration and residual contents

The phenomenon of migration of substances from food packaging is a complex problem. The certification of food safety is essential. The barrier effect of films and coatings is investigated. The determination of different ingredients and migration measurements under varying conditions are carried out. The conformity work is an essential element of self-control. The aim is to prove that the Food Contact Materials used comply with all food law requirements. Under the specified conditions of use, they may only release substances to food in quantities that are technically unavoidable and pose no health risk. Furthermore, they must not cause any change in the composition or organoleptic properties of the food.

2.1 Test conditions for migration tests due to the application

Simulant solvent	test simulant	Test conditions	
		time [days]	temperature [°C]
Distilled water	A	10	40
3% acetic acid (w/v)	B	10	40
10% ethanol (V/N)	C	---	---
50% ethanol (for dairy products)	D1	---	---
Fat (rectified olive oil / test fat HB 307)	D2	---	---
Alternative tests according to Directive 97/48/EC Isooctane Ethanol		10*	40* (Ethanol 95%)
MPPO (Tenax)	E	---	---

* 10 days // 40 °C (OM2) covers any storage period under refrigeration and freezing conditions, including heating to 70 °C for a duration of ≤ 2 hours or heating to 100 °C for a duration of ≤ 15 min. The OM2 test also covers the food contact conditions described for OM1 and OM3.

The inner layers of the composite films consist of polyethylene which has a plasticizing point of approx. 85 °C. When used above this temperature, the mechanical properties such as seal seam strength can be impaired.

2.2 Overall migration (OM)

The limit of 10 mg of constituents released in simulants per dm² of the surface in contact with foodstuffs is complied with under the above test conditions.

2.3 Specific migration limits (SML) and other restrictions

The SMLs and/or other restrictions prescribed by Regulation (EU) No 10/2011 (including the above mentioned amendments) are met under the test conditions mentioned. This applies using the highest O/V ratio that can be found. [O = surface plastic that comes into contact with V = volume of food for this analysis].

Compliance with the specific migration values is guaranteed by

- 1) Migration measurements according to the guidelines 821711 / EEC including the amendment 93/8/ EEC
- 2) Regulation 10/2011 /EU*, plastics in food contact *and EU 2017/752 (Annexes I-IV)
- 3) Supplier declarations and worst-case calculations

Substance	PM/Ref No	FCM Substance No	SML / restriction mg/kg
Caprolactam	14200	212	15
Hexamethylendiamin	18460	305	2.4
Isophorondiamin	12670	454	6
isophthalic acid	19150	291	5
Maleic anhydride	19960	234	30
1-hexene	18820	356	3
Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	433	6
Zinkoxid	96240	402	25
Tris(nonphenyl)-phosphite	74400	69	30
Stearic acid and zinc salts	89040	106	25
Phosphoric acid	74400	69	30

2.4 ingredients whose use in food is subject to a restriction (Dual Use additives³)

3) "Dual use substances" are substances intended to be used in both food contact materials and food contact materials. Food additives fall under the scope of Regulation (EC) 1333/2008 including Supplement.

These are the following substances

Substance	E No	Ref No	FCM Substance No
Talk	E 553b	92080	615
Silicone oil	E 900		
Glycerol	E422		
Silicon dioxide silicic acid	E 551	86240	504
Calcium carbonate	E 170		
Calciumstearat	E 470 a		

2.5 NIAS in food packaging

According to EU Regulation 10/2011, unintentionally introduced substances such as impurities, reaction products or degradation products should be indicated in the substance specification if they are relevant for the risk assessment. The introduction of such substances is avoided by the manufacturing processes.

2.6 Functional Barrier

Certain plasticisers such as phthalates are an undesirable contaminant in recycled paper. They enter the cycle via dispersion adhesives or varnishes. According to BfR Recommendation XXXVI, certain phthalates are subject to a restriction of migration into foodstuffs, compliance with which must be checked by analytical tests. A functional barrier is a multi-layer packaging structure in which one layer prevents or delays the mass transfer process of a migrating substance through the packaging into the food. If plastic layers are separated from the foodstuff by a functional barrier, they fulfil the requirements of Art. 13 No. 2, 3 and 4 or Art. 14 No. 2 and 3 of Regulation (EU) No. 10/2011.

3.0 Additional requirements for coloured plastics

Pigments used are in accordance with Council of Europe Resolution AP (89)1 "on the use of colorants in plastic material coming into contact with food".

3.1 Adhesives

not applicable, adhesives are not included.

4.0 Printing inks

For food packaging, only printing inks are used which comply with Regulation (EU) 10/2011 and have no relevance to health, or the print is applied between the film layers (functional barrier).

5.0 Hygiene

In the EU, FCM is subject to legal requirements for Good Manufacturing Practice (GMP) according to Art. 3 of the European FCM Framework Regulation (EC) 1935/2004 and the GMP Regulation (EC) 2023/2006. GMP in this context means conformity work along the entire manufacturing chain with a clear allocation of responsibilities.

An auditable hygiene, cleaning and pest control concept has been implemented. The products are manufactured under optimal hygienic conditions, taking into account potential hazards, the assessment of associated risks and a system to control identified hazards (chemical, physical and microbiological risks according to HACCP for food applications).

Due to the manufacturing process of tubular bags, the inner side facing the foodstuff never comes into contact with people or machine parts.

A hygiene certification according to HACCP and BRC/loP is available.

HACCP: hazard analysis and critical control points

BRC / loP: Standard for packaging materials for the food industry British Retail Consortium, Institute of Packaging

6.0 Microbiology

The material is free from pathogenic germs, other germs and mould (< 50 CFU/100cm²)

7.0 Heavy metals

The requirements of Directive 94/62/EC (including the amending Directives 2004/12/EC and 2005/20/EC) regarding heavy metal content are complied with.

8.0 Powder

Powders are not used.

9.0 Declaration on the exclusion of nanomaterials and microplastic

Definition: Nanomaterials are substances that are consciously designed and technically manufactured with the aim of obtaining specific properties (shape, surface or appearance) on the nanoscale (approx. 1-300 nm in at least one dimension) that are exclusively available on nanoscale¹. They are not used for our products.

¹) If necessary, particles with larger diameters can also fall into this category.

Randomly generated particles on the nanoscale, which can be produced by traditional processing methods such as homogenizing², grinding² or foaming² are excluded from this definition. Nanoscale particles occurring in the environment (e.g. volcanic or suspended dust) or in food (e.g. simple sugars, amino acids or fatty acids) are also excluded.

²) This process does not occur in the manufacture of our products.

When packaging food in plastic film, there is generally no abrasion³ or residue³ of as "microplastic" in food. Corresponding media reports lack any basis.

³) according to Art. 3, Para.1 EU Regulation 1935/2004 on materials intended to come into contact with foodstuffs.

This document has been translated for informative purpose. In case of doubt the German version is valid.

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.

30. May 2022



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

