

Technical Data Sheet/Declaration of Compliance

(According to European Community regulation 10/2011/EC - annex IV)

JOFOL 1 10018.035_BB-PP-di_Beutel

Valid for the following articles:

Sachets neutres avec un fond polypropylene

(1)Product(s):

bags made of BOPPC 35μ

- bags with a bottom sticker made of PP500μ or BOPPC20μ**/PP500μ

(2)General properties:

- raw material for bag production: biaxial orientated polypropylene (BOPPC) 35μ
- heat sealable
- good barrier against water vapour
- suitable for food contact (unprinted side of the film - the printed side of the film must not be in direct contact with foodstuffs) - see point 4 & 6 for details
- not qualified for pasteurisation, sterilization process, microwave, oven or similar thermal applications
- not / limited qualified for aggressive fillings (tea, spices,...)*

*.....the suitability of the packaging material when using it with aggressive fillings has to be tested by the customer with the original fillings and under real conditions

(3)Structure(from outside to inside):



Transparent or white PP500μ bottom sticker or a laminated bottom sticker of BOPPC20μ**/PP500μ - partially attached to the bottom on the outer surface of the bag



Printing inks (if printed)



Carrier layer: BOPPC 35μ

**....BOPPCmet20μ, upon request printed BOPPCmatt20μ or BOPPC transparent20μ

(4)Application according to 10/2011/EC:

Customer: FITER

Product(s): bags made of BOPPC 35μ

Suitable for the following filling(s): solid and dry fillings with/without fatty surface like confectionery, sweets, bakery products**

***this packaging specification is not intended for baby and infant/toddler/small child food according to the directives 2006/141/EC and 2006/125/EC*

Suitable for the following contact conditions filling/packaging material:

Long term storage at room temperature or below

The packaging product is not qualified for pasteurisation, warm and hot filling, sterilization process, microwave, oven or similar thermal applications.

Highest ratio of food contact surface area to volume used to establish the compliance of the material: 6dm² packaging material/1kg filling (euro cube model)

(5)Technical Data of the used BOPPC film:

Properties	Method	Unit	Typical Values
Thickness	Internal Method	μm	35*
Unit weight	Internal Method	g/m ²	31,9*
Water vapour permeability (WVTR)**	23°C – 85%RH DIN 53122	g/m ² /24h	< 1
Oxygen permeability (OTR)**	ASTM D-3985 23°C - 0%RH	cm ³ /m ² /d bar	1300
Heat seal range	Internal Method	° C	105 – 140
*...+/- 10%			
**...relating to the film material not to the bag			

(6)Health & Safety Guidelines:

With this document we certify, that the plastic film packing material is in conformity with:

- 1935/2004/ECC

The product complies with the relevant, applicable parts of the EU Framework Regulation 1935/2004/EC (article 3, article 11 paragraph 5, article 15 and article 17 are applicable).

- 10/2011/EC incl. all amendments / changes up to today

- 2023/2006/ECC

- 94/62/ECC (concerning heavy metals)

Printing Inks:

The used printing inks are in accordance with the *EuPIA Exclusion List for Printing Inks and Related Products* and CEPE „*Good Manufacturing Practices for the Production of Packaging Inks formulated for use on the non-food contact surfaces of food packaging and articles intended to come into contact with food* (“GMP”).

The composition of the printing inks is also in conformity with the Swiss regulation 817.023.21.

Adhesive:

The used adhesive is in conformity with at least one of the following regulations:

- 10/2011/EC or
- FDA 175.105 or
- Specific BfR- recommendation on adhesives

In the absence of a specific EU regulation for adhesives Article 16 of the framework Regulation (EC) No. 1935/2004 permits other European directives or national regulations for declarations of compliance.

The following substances that could be part of this specification are restricted to specific migration limits or other limits according to 10/2011/EC:

CAS No.:	FCM substance No.	Substance name	SML(mg/kg) & other restrictions
-	-	Aluminium	1
-	16	Alkyl(C 8-C 22)sulfonsäuren	6
-	19	N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)amin	SML(T) = 1,2
-	20	N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)aminhydrochloride	SML(T) = 1,2
-	95	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	No SML according to 10/2011/EC Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10 ⁻⁶ m ² /s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
000075-38-7	132	Vinylidene fluoride	5
000077-90-7	138	Tri-n-butylacetylacrylat	60
000077-99-6	141	1,1,1-Trimethylolpropan	6
000079-10-7	147	Acrylsäure	6
154862-43-8	156	Methylmethacrylat	6
000097-90-5	185	Ethylenglykoldimethacrylat	0,05
000098-54-4	186	4-tert-Butylphenol	0,05
000101-68-8	198	Diphenylmethan-4,4'-diisocyanat	ND / 1 mg/kg in final product expressed as isocyanate moiety
000103-23-1	207	Bis(2-ethylhexyl)adipat	18
000108-31-6	234	Maleinsäureanhydrid	30
000111-46-6	263	Diethylenglykol	30
000111-66-0	264	1-Octene	15
000116-14-3	281	Tetrafluorethylen	0,05
000116-15-4	282	Hexafluoropropylene	ND
000122-20-3	292	Triisopropanolamin	5
000128-37-0	315	2,6-Di-tert-butyl-p-kresol(=E321)	3
000141-32-2	325	n-Butylacrylat	6
000584-84-9	354	2,4-Toluoldiisocyanat	ND / 1 mg/kg in final product expressed as isocyanate moiety
000592-41-6	356	1-Hexene	3
000822-06-0	372	Hexamethylendiisocyanat	ND / 1 mg/kg in final product expressed as isocyanate moiety
002082-79-3	433	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionat	6
0004130-42-1	477	2,6-Di-tert-butyl-4-ethylphenol	4,8
007128-64-5	500	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophen	0,6
0010094-45-8	587	Octadecylceramid	5
026741-53-7	652	Bis(2,4-di-tert-butylphenyl) pentaerythritoldiphosphit	0,6
0027676-62-6	661	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazin-2,4,6(1H,3H,5H)-trion	5
038613-77-3	688	Tetrakis(2,4-di-tert-butylphenyl)-4,4'-biphenylen-diphosphonit	18
040601-76-1	689	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazin-2,4,6(1H,3H,5H)-trion	6
061788-89-4	705	Dimere von ungesättigten Fettsäuren (C 18), nicht hydriert, destilliert und nicht destilliert	0,05
068783-41-5	733	Dimere von ungesättigten Fettsäuren (C 18), hydriert, destilliert und nicht destilliert	0,05
119345-01-6	760	Reaktionsprodukt von Di-tert-butylphosphonit mit Biphenyl, erzeugt durch Kondensation von 2,4-Di-tert-butylphenol mit dem Friedel-Crafts-Reaktionsprodukt aus Phosphortrichlorid und Biphenyl	18
154862-43-8	773	Bis(2,4-dicumylphenyl) pentaerythritoldiphosphit	5
182121-12-6	779	9,9-Bis(methoxymethyl)fluoren	0,05
736150-63-3	783	Ester von hydrierten Rizinusölmonoglyceriden mit Essigsäure	60
0882073-43-0	808	Bis(4-propylbenzyliden)propylsorbitol	5
939402-02-5	974	Phosphorige Säure, gemischte 2,4-Bis(1,1-	10

		dimethylpropyl) phenyl- und 4-(1,1-Dimethylpropyl)phenyltriester	
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Substances according to Annex II, Table 1 of 10/2011/EC:

The requirements of 10/2011/EG including all additions/changes up to the present day (incl. 1245/2020/EG) for substances according to Annex II, Table 1 are met.

Information on primary aromatic amines:

The requirements of 10/2011 / EG including all additions / changes up to the present day (incl. 1245/2020/EC) for primary aromatic amines are complied with.

The Declaration of Conformity is based on:

- Supplier confirmations
- Overall migration analyses according to 10/2011/EG on equal or comparable specifications
- Specific analyses on equal or comparable specifications

The overall migration analyse was realized under the following conditions:

food simulant	test conditions	correspond with food contact conditions
Simulant D2 – Ethanol 95% instead of olive oil	10 days / 60°C***	Long term storage at room temperature or below***

*** According to 10/2011/EC – chapter 3, paragraph 3.1, table 3 the overall migration testing under test OM2 (“Any long term storage at room temperature or below”) has to be done with the testing conditions 10d/40°C. These conditions are covered by the more stringent test conditions 10T/60°C that we have used for the overall migration testing.

The overall migration result is below the limit of 10mg/dm².

Highest ratio of food contact surface area to volume used to establish the compliance of the material:
6dm²/1kg filling

The packaging product is suitable for direct food contact with the fillings and contact conditions listed in part 4 “Application” of this document. The migration limits (overall migration & specific migration) are met under the conditions described in part 4 “Application” of this document for applications to which the conventional ration of food contact area to volume of 6dm²/kg is applicable.

Other fillings and/or contact conditions are not covered by this declaration of conformity therefore the conformity of the packaging material for other fillings and/or contact conditions has to be checked by the customer himself.

List of dual use additives that could be part of this specification:

E172, E260, E304, E307, E321, E330, E422, E435, E444, E470a, E470b, E471, E475, E477, E504, E526, E530, E551, E553b, E570, E900, E1520, E1521

Note on Titanium Dioxide:

E171(Titanium Dioxide) is no longer authorized as a food additive in the EU since August 2022, however, the use of Titanium Dioxide in food contact materials is still authorized via 10/2011/EC.

Titanium dioxide may be included in this packaging specification.

Note on baby and infant/toddler/small child food:

This packaging specification is not intended for baby and infant/toddler/small child food in accordance with the guidelines 2006/141/EC and 2006/125/EC and was therefore not checked for the special requirements with regard to such foods.

Functional Barrier:

This package specification does not provide a "functional barrier" respectively it has not been checked to ensure their effectiveness as a "functional barrier".

Traceability:

In accordance with Article 17 of 1935/2004/EC, there is implemented a suitable system of traceability. Details are available on request.

NIAS:

For this packaging product we currently have no detailed information about NIAS from our raw material suppliers, our upstream suppliers do not disclose any NIAS substances to us. According to their statements, the manufacturers evaluate NIAS known to them via the risk assessment anchored and prescribed in EU Regulation 10/2011 / EC.

In the course of our conformity work, in addition to migration examinations, we carry out random checks(screenings) to check for NIAS of our packaging products via accredited test laboratories and conduct a risk assessment if necessary.

This Declaration of Conformity is applicable only on the materials that are used for the production of your packaging material. Substances as printing inks or self-adhesive labels which may be additional added by the customer or the packer are not covered by this declaration as well as labels provided by the customer. In such cases, the responsibility for checking the conformity of the final packaging product lies with the customer or with the party who provides us with the products or also adds them.

This information is based on our current knowledge and experience. In view of the many factors that may affect processing and application the customer must check that the use of our packaging material is safe and technically suitable in its application by himself.

The packaging producer is not responsible for any quality changes of the products in case of an interaction between the filling and the packaging material.

Usage:

Considering the recommended storage and processing conditions the bags are suitable for use up to 12 months from the date of production.

Recommended storage and processing conditions:

Storage conditions determine working properties exceedingly. Storage is recommended in closed places without direct sun contact, temperature between 15 and 25 °C and an atmospheric humidity of 40-70%.

The bags should be conditioned at room temperature for at least 48 hours before use/filling.

Run of validity of the statement:

This declaration is valid for the period of 12 months from creation date of this document, unless that it is replaced or repealed by an update.

Publisher of the statement:

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04/06/2024



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Sarl au capital de 15.244,90 €

The content of this declaration of conformity is strictly confidential and must not be disclosed to third parties. In the event that such information is required to conformity assessment or for migration tests, you are, on the condition that the information is kept strictly confidential, entitled to transfer that information to a public authority or an independent institution.

Note on safety:

This product is only for use as a packaging product/material. This product is unfit for consumption.