

Declaration of Compliance: Direct Food Contact Use

Information of the product

Selling name and identification data of the packaging material:

Paper bag for bread with plastic window

Structure of the packaging material:

The packaging material consists of bleached or unbleached kraft paper and OPP window film. The sealings and plastic window are glued with two different adhesives. Bag is produced to needed size and it can be printed. The paper and plastic can be in direct contact with food. Printing ink and adhesives meets the needs of indirect food contact use.

Intended use of the packaging material:

The packaging material is suitable for bakery products in general at room temperatures and below in any long-time application. It can be used with dry, moist and oily products. Customers should verify the suitability of the product for its specific end use. Not applicable holding food during cooking.

Handling and storage

Keep away from all sources of ignition when handling, transferring and processing the product. Keep in a cool (not below +0°C, maximum +30°C), dry, well ventilated place away from strong odors. Keep away from moisture.

Products have to be protected from direct UV-light. Improper storage can initiate degradation, which results in odor generation and colour changes and can have negative effects on physical properties of the products. Avoid sudden changes in temperature and acclimate to operating room temperature before use. We recommend using products within 12 months from manufacturing date.

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Operaattori / Operator: Itella Information Oy
Välittäjäätunnus / Operator address: 003710948874
Paperilaskut / Paper invoices: PL 20263, FI-00021 Laskutus



Analysis of the suitability of the raw materials for food contact use

(Based on declarations sent by producers)

Raw materials comply with the following regulations in force in Finland and other countries:

Paper:

- The European Parliament and the Council of the European Union Regulation (EC) 1935/2004
- Commission Regulation (EC) 2023/2006
- BfR-Empfehlungen A XXXVI, Papiere, Kartons und Pappen, für den Lebensmittelkontakt, Germany

OPP window film:

- The European Parliament and the Council of the European Union Regulation (EC) 1935/2004
- Commission Regulation (EC) 2023/2006
- Commission Regulation 10/2011
- EU Epoxy Derivatives Regulation – (EC) No 1895/2005
- EU Vinyl Chloride Monomer Directive – 78/142/EEC

A list of SML substances which can be found from OPP film:

Substance Identifier	FCM Substance No.	Substance Name	Specific Migration Limit (mg/kg)	Substance Status in Subject Products
R.1.1	19	N,N-bis(2-hydroxyethyl)alkyl(C ₈ -C ₁₈)amine	T = 1.2 (Group Restriction 7)	Standard
R.1.2	132	Vinylidene fluoride	5	Incidental
R.1.3	281	Tetrafluoroethylene	0.05	Incidental
R.1.4	282	Hexafluoropropylene	HD LoQ = 0.01 mg/kg	Incidental
R.1.5	652	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphate	0.6	Default
R.1.6	740	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazino-2,4-diyli]-[[2,2,6,6-tetramethyl-4-piperidyl]-imino]hexamethylene[[2,2,6,6-tetramethyl-4-piperidyl]imino]	3	Incidental
R.1.7	760	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl	18	Incidental

A list of dual-use substances which can be found from OPP film:

Substance Identifier	E Number	Additive Name	Authorising Directive	Annex	Restriction in Food	Purity Criteria Directive	Substance Status in Subject Products
D.1.1	E 470a	lIa, K, Ca salts of fatty acids	95/2/EC	I	quantum satis	2008/84/EC	Standard
D.1.2	E 471	Mono- and diglycerides of fatty acids	95/2/EC	I	quantum satis	2008/84/EC	Standard
D.1.3	E 551	Silicon dioxide	95/2/EC	IV	10g per kg	2008/84/EC	Standard

NOTES:

- The "Substance Identifier" is a reference that we have allocated to designate the restricted substance. The identifiers do not correspond to terms used in EU food contact, food additives or flavourings legislation.
- The entry in the "Substance Status in Subject Products" column indicates the basis on which the additive has been identified as applicable to the subject products.

This table defines the terms used in the column "Substance Status in Subject Products"

Designation	Meaning
Standard	The substance has been identified as applying to input materials that we use in all of the operationally qualified formulations for the manufacture of the subject products
Default	The substance has been identified as applying to input materials that we use in some of the operationally qualified formulations for the manufacture of the subject products, including the most common formulation in use at the effective date
Optional	The substance has been identified as applying to input materials that we use in some of the operationally qualified formulations for the manufacture of the subject products, but not the most common formulation in use at the effective date
Incidental	This means either: <ul style="list-style-type: none"> the substance can be present in consignments of the subject products because of the use of recovered polymers for the manufacture of the base sheet, as permitted by our quality control system and consistent with the principles of good manufacturing practice; or: <ul style="list-style-type: none"> the substance is a production aid, and is not intended to accomplish a technical effect in the subject products



Adhesives:

- The European Parliament and the Council of the European Union Regulation (EC) 1935/2004
- Commission Regulation (EC) 2023/2006
- EC Regulation 10/2011/EC as amended by Regulation 1282/2011/EC

Above mentioned EU legislation is not fully applicable for adhesives but when glues are fully cured it may comply with specific migration limits.

A list of SML substances which can be found from adhesive:

Ref. No	CAS No	Substance name	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)
10060	0000075-07-0	Acetaldehyde	6	
10120	0000108-05-4	Acetic acid, vinyl ester	12	
11470	0000140-88-5	Acrylic acid, ethyl ester		(22)
13630	0000106-99-0	Butadiene	ND	
17050	0000104-76-7	2-ethyl-1-hexanol	30	
17260	0000050-00-0	Formaldehyde	15	
22210	0000098-83-9	α -methylstyrene	0,05	
66755	0002682-20-4	2-Methyl-4-isothiazolin-3-on	0,5	
93280	0000693-36-7	Thiodipropionic acid, dioctadecyl ester		(14)
19540 64800	0000110-16-7	Maleic acid		(3)
22660*	0000111-66-0	1-octene	15	
----- ³⁾	0078330-30-0	Emulgator		
37520 ⁴⁾	0002634-33-5	1,2-Benzisothiazolin-3-one	0,5	
40320 ¹⁾	0010043-35-3	Boric Acid (E284)	6	
43760 ²⁾	0026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	0,0003mg/dm ² dispersionsfilm	
46640 ¹⁾	0000128-37-0	2,6-Di-tert-butyl-p-kresol (BHT, E321)	3	
86240 ¹⁾	0007631-86-9	Silicon dioxide		
86640 ⁵⁾	0009004-32-4	Sodium carboxymethylcellulose (E446)		

* in traces

1) This additive is also a food additive or flavouring

2) Not listed in the plastic Directive, but in BfR XIV with restrictions, Ref.no. from Synoptic Document 2005.

3) Not listed in the Plastic Directive, but in BfR XIV

4) Not listed in the Plastic Directive, but in the Synoptic Document June 2005 (EFSA opinion SDS EFSA/ AFC/FCM 605-Rev.IIB/37520 of 2007)

5) Not listed in the Plastic Directive, but in the Synoptic Document June 2005, GRAS 21 CFR 182.1745.

Printing inks:

- The European Parliament and the Council of the European Union Regulation (EC) 1935/2004
- Commission Regulation (EC) 2023/2006
- EC Regulation 10/2011/EC

The product is developed to use in places where ink do not come in direct contact with food so normal packaging legislation is not applicable and there is no specific EU legislation on printing inks.

The product is manufactured using GMP-principles and the raw materials are selected according to EuPIA (European Printing Ink Association) exclusion list draft.



There are no substances, which are on the exclusion lists of SBPIM (Society of British Printing Ink Manufacturers) and VdD (Verband der Druckfabenindustrie / German Association of Printing Ink Manufacturers) used as raw materials in the inks. Azo dyes and phthalate esters are not used.

Pigments are not based on heavy metals; they meet the purity requirements of the CoE Resolution AP(89)1 or the BfR Recommendation IX with regard to heavy metal contaminants. According to the statements of the suppliers of the raw materials, the pigments meet the requirements concerning heavy metal impurities of the EC Directive 94/62/EC and the US Regulations of CONEG.

Migration and other tests

Product is tested with simulant E for 10 days in +40°C. The overall migration limit 10 mg/dm² was maintained with simulant. In addition, SML and printing ink compound migration are verified by screening with GC-MS after 10 day +40°C migration to simulant E.

Overall migration tests are performed for OPP window film with following simulants and test conditions. Migration limit 10 mg/dm² was maintained with all simulants.

OPP window film:

Food simulants	Test conditions	Time temp.(°C)	Result (mg/dm²)	Test method
3% w/v aqueous acetic acid,	10 days	40	<10	EN 1186
20 % v/v aqueous ethanol	10 days	40	<10	EN 1186
50% v/v aqueous ethanol	10 days	40	<10	EN 1186
rectified olive oil	10 days	40	<10	EN 1186

Legislation, chemical legislation, environment and traceability

EU Legislation and traceability

The product fulfills the frame regulation 1935/2004 for food contact materials. Also regulation 2023/2006 is followed. Local public authorities are monitoring the factories regularly. Products are traceable according to their manufacturing number which can be found from the product label. . Factory is ISO 9001, 14001, 22000 and EN 15593 certified.

REACH

The product is free of substances of very high concern in regard of 1907/2006/EC.



Waste

The product can be used as a source of energy, product is in accordance of 94/62/EC as amended.

This statement is valid until substantial changes in the production bring changes in the migration, when new scientific data are available, or if legislation brings changes in the content of this declaration.

For more information, take contact to your dedicated sales person.