



Datum: 25.08.2025

Declaration of Conformity with the Requirements of Food Contact Legislation

We are supplying you with the following material / product:

Products (cuts) made of OPP; unprinted (KE1800)

Material: Polypropylen (PP)

Article: The article classification (number of article and article description applicable for the declaration of conformity) is available on our homepage in the download block.

This product complies with the following legal requirements or recommendations:

Generally

- EU-Framework Regulation on materials and articles intended for food contact: (EC) No 1935/2004
- Commission Regulation (EC) No 2023/2006 on Good Manufacturing Practice (GMP)
- Additionally for German customers: LFGB §§ 30 and §§31

Raw Materials / Composition

· Plastics

EU-Legislation

- Commission Regulation (EU) No 10/2011 as amended by date
- Including Annex II of Regulation (EU) 10/2011



Conditions of use / Compliance with threshold values

Suitability for Food

This material may only be used for the following applications:

All types of food according to (EU) 10/2011 // Simulant(s) A+B+D2+E

Time and Temperature of Storage and Converting

The above mentioned products are suitable for the following food contact conditions:

- OM1: Any food contact at frozen and refrigerated conditions.
- OM2, 40dgrC: Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{(T-70)/10}$ minutes.

The applied Surface/Volume-Ratio in dm^2/kg food for this food contact packaging is: **6.0**

The calculated maximum Surface/Volume-Ratio in dm^2/kg food for this application is: **6.0**

Overall Migration

The level of Overall Migration was determined using the following test conditions:

Simulant / Kontaktzeit	Migration mg/dm^2
Simulant B: Acetic acid 3%, 10 days @40°C	< 10
Simulant A: Ethanol 10%, 10 days @40°C	< 10
Simulant D2: Vegetable Oil, 10 days @40°C	< 10

The observance of the global migration values according to the requirements of Commission Regulation (EU) 10/2011 as amended by date produces values below the allowed threshold (for the above-mentioned conditions of use) of $10\text{ mg}/\text{dm}^2$.



Specific Migration

Some or all of the restricted substances listed in the following table may be present in the finished material:

PM/ ref. Nr.	FCM Subst. No.	CAS-No.	Substance	Restriction	
				mg/kg*	Group SML
95360	661	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)- trione	5	
83595	760	0119345- 01-6	reaction product of di-tertbutylphosphonite with biphenyl, obtained by condensation of 2,4- di-tertbutylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	18	
39815	779	0182121-12-6	9,9-bis(methoxymethyl)fluorene	0,05	
68320	433	0002082- 79-3	octadecyl 3-(3,5-di-tertbutyl-4-hydroxy-phenyl) propionate	6	
39090	19	-----	N,N-bis(2-hydroxyethyl)alkyl(C8C18)amine		7

*Total migration of Group SML if applicable.

Specific information as obtained from suppliers and a worst case calculation and/or migration measurements indicate that all migration limits are met.

Dual Use Additives

As required by COMMISSION REGULATION (EU) No 10/2011 as amended the following table identifies substances used in plastics and subject to a restriction in food through an authorisation as food additive or flavouring.

PM/ ref. No.	FCM Subst. No.	CAS-No.	Substance	E number
-----	-----	-----	Calcium salts of fatty acids	-----
86240	504	0007631-86-9	Synthetic Silica	E551

Further Declarations

Compliance to Norms

The material is compliant to the following norms:

- | | |
|---|---|
| Commission Regulation (EC) No 282/2008 | of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods |
| Commission Regulation (EU) 2015/1906 | of 22 October 2015 on recycled plastic materials and articles intended to come into contact with foods (|
| Commission Regulation (EC) No. 450/2009 | of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food |
| BfR Recommendations: | VII. Polypropylene as of 01.06.2019. |
| Directive 94/62/EC Packaging and Packaging Waste Directive, | amended by Regulation (EC) №1882/2003, Directive № 2004/12/EC, Directive № 2005/20/EC, Regulation (EC) №219/2009, Directive № 2013/2 EU, Directive (EU) № 2015/720, Directive (EU) № 2018/852 for heavy metals present in the packaging and their release into the environment; dangerous substances present in the packaging and their release into the environment. |
| Italian Regulations: | D.M. 21/03/1973 and following revisions and amendments,
DPR 777/82 and following revisions and amendments, UNI 13430/2005 |
| Canadian Food and Drug Regulations | Division 23 – Food Packaging Materials |
| Switzerland Regulation BGVO 817.023.21: | of 23rd November 2005, and revised version of the Ordinance on Materials and Articles in contact with food (817.023.21), which came into force on 1st May 2017 and all subsequent amendments including Annex 10, Edition 2.1, entry into force on 1 December 2020. This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE" |
| France Regulation | According to the information received from our suppliers, films meets the requirements of Decree No 2007-766 of 10 May 2007, amended by the Decree No 2008-1469 of 30 December 2008. |

California Safe Drinking Water and Toxic Enforcement Act of 1986

Based on the information from our raw material suppliers, we certify that the films do not contain any cancer causing or reproductive toxicity chemicals. To the best of our knowledge, none of the substances listed in the "California Proposition 65 List of Chemicals and its subsequent amendments up to the Chemicals Listed Effective Feb 25, 2022 pursuant to the California Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as California Proposition 65) are used or intentionally added.



Further Declarations

Compliance to Norms

The material is compliant to the following norms:

US Food and Drug Administration (FDA)

The products meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 for Olefin polymers and are manufactured exclusively from FDA-approved materials. All components comply with the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), under title 21 with sections as: 174.5; 178.3130; 178.3860; 178.2010; 182.1711; 184.1033; 184.1324. According to the information received from our suppliers the base resins in this products meet the FDA requirements in 21 CFR 177.1520 (a) (1)(i) and (c)1.1a. According to the information received from our suppliers this product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to information, these substances used in this product meet the requirements of their respective FDA regulations, FCNs, and 21 CFR 177.1520(b). This products meet the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1

MERCOSUR

According to the information provided by the raw material suppliers, the base resins used in the production of the films meet the relevant requirements of:

- GMC Resolution No. 03/1992 of April 1st 1992, which establishes the general criteria and classification of materials for packaging and equipment in contact with food.
- GMC Resolution No 02/2012 of April 19th 2012, which provides a positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food.
- GMC Resolution No 39/2019 of July 15th 2019, which provides a positive list of additives for plastic materials for the preparation of plastic materials and polymeric coatings in contact with food.

According to the information received from our raw material suppliers the monomers and additives used to produce the base resin used in production of BOPP films are listed in Part I: "List of monomers and other authorized starting substances" of GMC Resolution No 02/1992 and in the "Positive list of additives for plastic materials for the preparation of plastic materials and polymeric coatings in contact with food" of GMC Resolution No 39/2019 respectively.

PR China

According to the information received from our suppliers the additives and PP Homopolymers and terpolymers, used for the production of films do not contains any substances which are regulated with a restriction in their use. All intentionally added substances contain only substances that are subject to PRC National regulating standards and are listed on this standards as follow:

- GB 4806.1-2016 General safety requirements for food contact material and articles
- GB9685-2016 Standard for uses of additives in food contact materials and articles
- GB 4806.7-2016 National Food Safety Standard for Plastic Materials and Articles in Contact with Foodstuffs
- GB 4806.6-2016 National Food Safety Standard for Resins Used to Make Plastics in Contact with Foodstuffs - Appendix A - 74 Polypropylene homopolymer

NIAS

The professional discussion about Non Intentionally Added Substances (NIAS) like Impurities, Reaction Products, Residues, Degradation Products is intensively followed by our company. However we did not determine any safety risks of our packaging material up to this date. At the same time we did not receive any specific indication about such safety risks.

We keep very close relationships to our suppliers in this as well in as in other regulatory questions. Following FPE's Code for Good Manufacturing Practise (Version 6.0, p.18) we may assume that our suppliers cover this problem on the level of incorporated raw materials via risk assessments referring to internationally recognized scientific standards (see Regulation (EU) 10/2011 (18) and (20)).

At tangible indications about hazards we have suitable instruments at our disposal. These include exposure studies following the achievements of the Exposure Matrix Group or EU's FACET project. Please feel free to contact us on this.

Information on Functional Barrier

The articles supplied do not contain a functional barrier.

Conclusion

In terms of EU-framework Directive (EC) No 1935/2004 and Commission Regulation (EU) 10/2011, there are no objections against the use of the product for the manufacture of articles intended for food contact.

This confirmation applies to the goods delivered by the supplier. The verification if the packaging or packaging film is suitable for the intended purpose of use and the filled good is subject to the user, i.e. the packaging manufacturer is not responsible for quality modifications of the packed food due to chemical reactions with the packaging material or its components. It is expressly pointed out that any contact between printing ink and food must be avoided.

This declaration is valid for one year.

With kind regards

Perga GmbH

(This document was created electronically and is valid without signature.)