

THE KULLAPLAST GUIDE TO THE NORMPACK CERTIFICATE

Kullaplast AB produces polyethylene film products for packaging and protection. Some of these products are used in food contact applications. In order to secure public health as well as food quality we have performed Worst Case Calculations and Migration Tests according to *Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food*, including corrections and amendments.

Calculations and tests were performed in collaboration with *The Trade & Industry group Normpack* at *RISE – Research Institutes of Sweden* and include those of our products that are intended for food contact applications. The setup of the migration tests is governed by Commission Regulation (EU) No 10/2011. Herein simulants and test conditions for different types of food is specified. We performed tests covering all food types and the use of our products for packaging and protection at room temperatures and below (N.B. not hot-fill).

N.B. No material or product is intended for heating, cooking, use in microwave ovens or similar.

For a statement regarding Legal Compliance and a General Absence Declaration, please refer to the Product Data Sheet and the document *Kullaplast AB - Regulatory Compliance and General Product Information*. The latest version of this document can be found on our [website](#).

If you have further questions, you are always welcome to contact our Quality Manager, see contact information below. Thank you for your interest in Kullaplast AB and our products.

Höganäs, Sweden, 2022-04-06



Staffan Hellsén, Ph.D., QHSE Manager.



NORMPACK CERTIFICATE

Registration number: 082 03 100 4642 38

Valid until: 2024-03-18

DESCRIPTION	Company / address	Kullaplast AB Box 62, 263 21 Höganäs
	Trade Name (type and/or art.no)	Polyethylene (LDPE), thickness 0-100 µm (certificate covers raw material composition groups corresponding to TO10605, TO10607 and TO10822)
	All layers in the material, starting with food contact layer	Polyethylene
	Substances with restrictions / SML	On request
	Dual use substances	On request
Functional barrier according to (EU) No 10/2011	No	

Assessed according to:	(EC) No 1935/2004 Framework regulation (EU) No 10/2011 Plastics regulation
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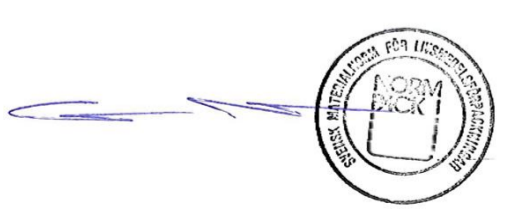
SUITABILITY	Evaluated and suitable for food types:	All food types
	Evaluated and suitable for time and temperature:	OM2 conditions: Long term storage at room temperature and below
	Single use / Repeated use	Single use
	Other restrictions and specifications	Not intended for any kind of heating or hotfill. Not to be used in conventional oven or microwave oven

TESTS / CALCULATIONS	Overall Migration	Overall migration has been performed on representative samples to food simulants A:10% Ethanol, B:3% Acetic acid and D2:Veg.oil < 1% unsaponifiable matter at conditions OM2 10 days 40°C. Result < 10 mg/dm ²
	Specific migration	Specific migration has been evaluated by worst case calculation and analysis. Specific migration analysis has been performed on representative samples to relevant food simulants B:3% Acetic acid, 10 % EtOH, 95% EtOH and isooctane at conditions 10 days 60°C. Results < SML mg/kg Metals in Annex II of (EU) No 10/2011 < SML PAAs in Annex II of (EU) No 10/2011 < SML
	Set off	Not applicable
	Surface to volume	Surface to volume ratio applied 6 dm ² per kg of food
	Organoleptic properties	Organoleptic properties have not been evaluated

VERIFICATION

Examined by Normpack's secretariat, ensuring that the above material(s) / product(s) at the time of issue of the certificate is/are consistent with the material specific requirements in the Normpack Norm (see back page of certificate) and that a complete documentation does exist. The processor is responsible for fulfilling all legal requirements. This certificate is valid for two years provided that no changes are made in the composition of the material or in the relevant legal requirements. For verification of validity, contact normpack@ri.se.

2022-03-18



Susanna Andersson

NORMPACK

THE NORMPACK NORM
amended 2021-11-05

- § 1. Materials and articles in contact with food shall meet the demands of Swedish or EU harmonized regulations, as amended:

Swedish regulations	EU-regulations - all materials	EU-regulations - specific materials
SFS 2006:804 SFS 2006:813 LIVSFS 2011:7 (Contact with Foods)	(EC) 1935/2004 (Framework reg) (EC) 2023/2006 (GMP) (EC) 178/2002 (General Food Law) (EC) 1333/2008 (Additives) (EC) 1334/2008 (Flavourings)	(EC) 450/2009 (A&I packaging) 84/500/EEC (Ceramics) 2007/42/EC (Cellophane) 93/11/EEC (N-nitrosamine) (EC) 1895/2005 (Epoxi) (EU) 10/2011 (Plastic) (EC) 282/2008 (Recycled plastic) (EU) 2018/213 (Plast-BPA)

- § 2. For materials not covered by Swedish or EU harmonized food contact material regulation, one of the following regulations should be used:

Warenwet	BfR	FDA
The Dutch Packaging and Food-Utensils Regulation (Warenwet), Netherland	Empfehlungen des Bundesinstitutes für Risikobewertung (BfR), Germany. Recommendations on	Code of Federal Regulations, Title 21 Food and Drugs, (FDA), USA §§ 174, 175,

- § 3. To ensure correct use, suppliers and purchasers throughout the value chain shall confer about the suitability of the material/article for the intended purpose.

- § 4. The transfer of constituents from the food contact material to food shall be assessed. If there is a limit regulating materials/articles, the following alternative methods are suggested to establish whether the material/article meets the demands:

- Worst case calculations
- Migration modelling
- Laboratory measurements

All in the Normpack Norm applicable laws and recommendations shall be applied in their latest updated version when issuing a certificate

Contact: normpack@ri.se www.normpack.se