



NORMPACK CERTIFICATE

Registration number: 317 12 100 4542 37

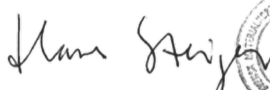

Valid until: 2023-12-22

DESCRIPTION	Company / address	GAIA BioMaterials AB, Bunkagårdsgatan 13 SE- 253 68 Helsingborg, Sverige
	Trade Name (type and/or art.no)	Biodolomer® Film
	All layers in the material, starting with food contact layer	Compound of PBAT and Calcium Carbonate
	Substances with restrictions / SML	CAS rn 100-21-0, 822-06-0, 110-63-4, 109-99-9
	Dual use substances	E 170
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:	OM1 conditions: Any food contact at frozen and refrigerated conditions. Also Room temperature at max 30 days.
	Single use / Repeated use	Single use
	Other restrictions and specifications	Film thickness 10 to 120 microns

TESTS / CALCULATIONS	Overall Migration	Overall migration has been performed on the whole construction by immersion to food simulants A:10% Ethanol, D2 Isooctane at conditions OM1; 10 days 20°C. And D2: 95% Ethanol 1 day 20°C. Results < 10 mg/dm2
	Specific migration	Specific migration has been performed on the whole construction by analysis. to food simulants at conditions 10 days 40°C. A: 10% Ethanol, (CAS 109-99-9, 110-63-4) B:3% Acetic acid, (metals and PAA) D1:50% Ethanol, (CAS 100-21-0) Screening of residual content of Isocyanate. Result Not detected 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 dm2 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.	2021-12-22
		  Hans Steijer

NORMPACK

THE NORMPACK NORM
amended 2019-10-29

- § 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 (Epoxy) (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