

Declaration of Conformity for food packaging films

We confirm that the films supplied by us:

AMILEN B-PA/PE (transparent / blue / black)

Flexible cast film based on polyamide and polyethylene

meet the following legal requirements in the relevant versions valid at the point in time at which this declaration was issued:

- Regulation (EC) No. 1935/2004
- Regulation (EU) No. 10/2011, including subsequent amendments
- Regulation (EU) No. 2020/1245
- Regulation (EC) No. 2023/2006 (GMP), including subsequent amendments
- German Food and Feed Code (LFGB) of 01.09.2005
- German Consumer Goods Ordinance
- BfR- Instructions of Federal Institute for Risk Assessment
- Directive 94/62/EC, including subsequent amendments (concentration of heavy metals < 100 ppm)
- Packaging law

Use of the Films

a) Types of foodstuffs that are permitted to come into contact with the films:

- all types of foods

b) Tested substance:

Substances	Test Conditions
A (ethanol 10 Vol.-%)	OM 2
B (acetic acid 3%)	OM 2
D2 (vegetable oil)	OM 2

c) For storage of the flat films without contact with the contents, we recommend compliance with the following storage conditions with regard to optimal processing:

- a. Storage temperature of 18 – 25 °C in original packaging
- b. Dust-free, dry indoor environment protected against UV radiation at 40 – 60 % relative humidity.

The maximum shelf life under the listed conditions until processing is 12 months from production date. For films with antifog-agent it is 6 months from production date.

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We recommend that the rolls are preconditioned to the specified storage conditions for 24 h prior to processing.

Improper storage can lead to a deterioration of the properties of the flat films in further processing.

d) Duration and temperature of treatment and storage with contact with the foodstuff:

- 70 °C for max. 2 hours
- the composite film can be frozen down to – 25 °C
- any long term storage at room temperature or below
- suitable for gamma rays <25 kGy and EO sterilisation

Conformity

Conformity was ascertained by:

- worst-case-calculations
- confirmations of the suppliers
- migration test

Herewith we confirm the compliance with the values of the overall migration (OML) and specific migration limits (SML) which are expressed in the following list. These values are specified in mg/kg using a ratio of surface to volume of 6 dm²/kg foodstuff.

List of substances contained with specific migration limits (SML)

FCM	Substance	CAS	Ref. No.	Specific Migration Limit SML [mg/kg]
69	phosphorous acid, tris(nonyl- and/or dinonylphenyl)ester	0026523-78-4	74400	30
212	caprolactam	0000105-60-2	14200 41840	15
234	maleic anhydride	0000108-31-6	19960	30
356	1- hexene	0000592-41-6	18820	3
402	zinc oxide	0001314-13-2	96240	5
433	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	0002082-79-3	68320	6
---	aluminium	0007429-90-5	---	1
---	antimony	0007440-36-0	---	0,04
---	arsenic	0007440-38-2	---	ND
---	barium	0007440-39-3	---	1

VF Verpackungen GmbH
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valid: 12 months from date of issue

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---	cadmium	0007440-43-9	---	ND
---	chromium	0007440-47-3	---	ND
---	cobalt	0007440-48-4	---	0,05
---	copper	0007440-50-8	---	5
---	europium	0007440-53-1	---	0,05
---	gadolinium	0007440-54-2	---	0,05
---	iron	0007439-89-6	---	48
---	lanthanum	0007439-91-0	---	0,05
---	lead	0007439-92-1	---	ND
---	lithium	0007439-93-2	---	0,6
---	manganese	0007439-96-5	---	0,6
---	mercury	0007439-97-6	---	ND
---	nickel	0007440-02-0	---	0,02
---	terbium	0007440-27-9	---	0,05
---	zinc	0007440-66-6	---	5
---	sum of lanthanides	---	---	0,05

DUA (Dual use additives)

FCM	Substance	CAS	Ref. No.	EC-No.
139	citric acid	0000077-92-9	14680 44160	E 330
504	silicon dioxide	0007631-86-9	86240	E 551

The information on the chemical substances with restrictions and on those to be regarded as "dual-use" additives, according to the European Plastics Converters (EuPC Study on dual use additives, version 02/2006), are based upon the information and declarations from our suppliers of raw materials and represent our current state of knowledge.

We follow developments in the relevant laws carefully and will inform the purchaser of any important changes in laws and standards that are of significance in connection with the manufacturing and use of the product. Adherence to the restrictions of the named or quoted regulations, including global migration, and suitability for the intended purpose are to be tested by the user on the completed item.

NIAS (Not intentional added substances)

NIAS are non-intentionally substances that are added in the manufacture and marketing of materials and articles made of plastic. These can be caused by impurities in the substances used, degradation or reaction products during the manufacturing process or as reaction interim products.

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Whether the non-intentionally added substances correspond to Section 3 of the Regulation (EC) No. 1935/2004 or not must be assessed in accordance to the internationally recognized scientific principles via risk assessment (see Section 19 of Regulation (EU) No. 10/2011).

The NIAS screening was performed by gas chromatography and flame ionization detector (GC-FID) according to the internal standard.

After toxicological evaluation the measured values of these substances complies with the requirements of the Regulation (EU) No. 10/2011.

Contents

Phthalats, adiphates, bisphenol A, bisphenol S, phosphates or polyester are neither used by us nor by our suppliers in their supplied products.

All our films comply with Annex I of 10 / 2011 EC regarding Table 1 of authorised substances and their listed SML.

All our films comply with Annex II of 10 / 2011 EC regarding the SML for metals and primary amines.

Only small amounts of powder will be used in the production process. It is free from GMO, gluten and other allergenic substances.

REACH

Our AMILEN films do not contain any substances of very high concern (SVHC list/ECHA) in a concentration above 0.1 % (w/w) according to art. 57 of Regulation (EC) No. 1907/2006.

Hygiene

We are certified to the BRCGS packaging materials.

Sensory

Our films are produced in compliance with the GMP Regulation (EC) No. 2023/2006 article 3, letter a and meet the requirements of Regulation (EU) No. 10/2011 and the Regulation (EC) No. 1935/2004 article 3, letter c and is therefore suitable under the mentioned conditions, to come in contact with food.

Based on these regulations, it is up to the user to check the technical and sensory suitability for a specific purpose.

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Recycling

Our AMILEN films are recyclable according to European Parliament and Council Directive 94/62/EC.

Microbiology

Microbiological status was ascertained by microbiological analysis. All measured values of yeasts, molds, enterobacteria and germs are below the detection limits (<3 CFU/ 100 cm²).

Allergens/ Genetically Modified Organisms (GMO)

We hereby confirm the absence of any allergenic substances listed in Regulation (EU) No. 1169/2011 Annex II and GMO`s which are neither used by us nor by our suppliers in their supplied products.

Heavy metal

The films are in compliance and fulfill the heavy metal directive 94/62/EC (including subsequent amendments).

FDA

We hereby confirm - based on the information provided by the raw material suppliers - that for the above mentioned AMILEN films the ingredients of the specification and their composition are in compliance with the approval of the United States Food and Drug Administration (US FDA):
FDA 21 CFR § 174.5, §175.105, § 176.170, § 177.1500, § 177.1520, § 177.1350, § 177.1395, § 178.3297 and § 178.3400 as valid at the date of issue of this certificate.

Nanomaterials

For the production of our AMILEN films no nanotechnology is used which means that the supplied products don`t contain any nano-scaled particles (< 300 nm).

MOSH/ MOAH

The migration of MOSH / MOAH substances into packaged products can be excluded for our AMILEN films due to PA barrier layers.

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The layer-structure of our AMILEN films consisting of various PA / PE layers forms an effective barrier to the migration of external influences.

At the same time, these barrier layers ensure a high quality and long-lasting freshness of the packaged food.

By our GMP manufacturing practice we make sure no mineral oil residues can occur within our process sequences.

We hereby confirm that our AMILEN films are very suitable for direct contact with foodstuffs of all kinds. The results of our in regular intervals carried out migration analysis confirm this fact.

Traceability

The traceability of our products (Regulation (EC) No. 1935/2004) can be guaranteed by our order / batch number.

This description applies to the product supplied by us, as described. According to this, the product, by meeting the stated foodstuff contact conditions, fulfills the requirements of this directive for the packaging of the stated contents.

The verification of the suitability of the films for the particular application lies in the responsibility of the customers and the distributor.

Date: 05.09.2023

Signature: 
Name: Sabine Höpfling
Quality management

Product: AMILEN B-PAPE transparent / black / blue
Description: Pouch films
Structure: polyamide-polyethylene PA/PE

erstellt: 29.01.2020
 geändert: 24.06.2023
 Version: 6.0

TECHNICAL DATA:

Properties	Method	Unit	Tolerances	65	75	85	100	100	70	80	85	90	100	100	120	130	140	100	130	140	
Thickness	DIN ISO 4593	µm	± 10 %	15/50	15/60	15/70	15/85	15/85	20/50	20/60	20/65	20/70	20/80	20/100	20/110	20/120	20/120	30/70	30/100	30/110	
Weight per area	DIN 55540-6	g / m ²	± 10 %	63.1	72.3	81.9	95.3	95.3	68.8	78.0	82.6	87.2	96.4	114.8	124.0	133.2	133.2	96.5	126.2	135.4	
Yield	---	m ² / kg	± 10 %	15.9	13.8	12.2	10.5	10.5	14.5	12.8	12.1	11.5	10.4	8.7	8.1	7.5	7.5	10.1	7.9	7.4	
Tensile strength	DIN ISO 527-1/-3	N / 15 mm length direction cross direction	---	≥ 40 ≥ 30	≥ 40 ≥ 30	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 45 ≥ 35	≥ 55 ≥ 45	≥ 55 ≥ 45	≥ 60 ≥ 45	≥ 65 ≥ 55	≥ 65 ≥ 55	≥ 70 ≥ 60	≥ 70 ≥ 60	
Elongation at break	DIN ISO 527-1/-3	in % length direction cross direction	---	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 200 ≥ 250	≥ 250 ≥ 350	≥ 250 ≥ 350	≥ 250 ≥ 350	≥ 250 ≥ 350	≥ 250 ≥ 350	≥ 250 ≥ 350	≥ 250 ≥ 350	≥ 300 ≥ 350
Seal strength	VF / DIN 55529	N / 15 mm	---	> 20	> 22.5	> 25	> 27.5	> 27.5	> 27.5	> 27.5	> 27.5	> 30	> 30	> 32.5	> 32.5	> 32.5	> 32.5	> 32.5	> 32.5	> 32.5	
Water vapour permeability	calculated	g / (m ² · 24 h) 85 % r.F. / RH 23 ± 2 °C	---	< 5	< 5	< 5	< 5	< 5	< 4	< 4	< 4	< 4	< 4	< 4	< 4	< 4	< 4	< 3.5	< 3.5	< 3.5	
Oxygen permeability	ISO 15105-2 DIN 53380-3 ASTM D3985	cm ³ / (m ² · 24h · bar) 50 % r.F. / RH 23 ± 2 °C	---	< 60	< 60	< 60	< 60	< 60	< 55	< 55	< 55	< 55	< 55	< 45	< 45	< 45	< 45	< 40	< 35	< 35	
Nitrogen permeability	calculated	cm ³ / (m ² · 24h · bar)	---	< 15	< 15	< 15	< 15	< 15	< 14	< 14	< 14	< 14	< 14	< 11	< 11	< 11	< 10	< 8.75	< 8.75	< 8.75	
Carbon dioxide permeability	calculated	cm ³ / (m ² · 24h · bar)	---	< 300	< 300	< 300	< 300	< 300	< 275	< 275	< 275	< 275	< 250	< 225	< 225	< 200	< 200	< 175	< 175	< 175	
Width	---	mm	± 1																		
Length	---	m	± 2 %																		



The product meets the legal requirements for food packaging:
 1935/2004/EC, VO (EU) Nr. 107/2011 including subsequent amendments,
 BFR and German Food and Feed Code (LFGB).

APPLICATION:

Suitable for applications at 70 °C for max. 2 h; Suitable for freezing down to -25 °C
 The material is not corona treated; Suitable for gamma irradiation < 25 kGy and EO sterilisation
 Minimum shelf life: 12 months from production date

Note for the end-consumer: Film packaging is unfit for consumption. Remove film before consumption. Do not overheat. Note the applicable national recycling regulations. Take care of the environment.
 These information correspond to our actual knowledge. The information and data contained in this document are in all conscience.
 However, no liability, warranty or guarantee is given. The verification of the suitability of the films for the particular application lies in the responsibility of the customers and the distributor.
 The document is provided electronically and is valid without any signature.



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Product: AMILEN B-PAPE transparent / black / blue
Description: Pouch films
Structure: polyamide-polyethylene PA/PE

erstellt: 29.01.2020
 geändert: 24.06.2023
 Version: 6.0

TECHNICAL DATA:

Properties	Method	Unit	Tolerances	150	160	200
Thickness	DIN ISO 4593	µm	± 10 %	30/120	30/130	30/170
Weight per area	DIN 55543-6	g / m ²	± 10 %	144,6	153,8	190,6
Yield	---	m ² / kg	± 10 %	6,9	6,5	5,2
Tensile strength	DIN ISO 527-1/-3	N / 15 mm length direction cross direction	---	≥ 70 ≥ 60	≥ 70 ≥ 60	≥ 80 ≥ 70
Elongation at break	DIN ISO 527-1/-3	in % length direction cross direction	---	≥ 300 ≥ 350	≥ 300 ≥ 350	≥ 300 ≥ 350
Seal strength	VF / DIN 55529	N / 15 mm	---	> 35	> 35	> 35
Water vapour permeability	calculated	g / (m ² · 24 h) 85 % r.F. / RH 23 ± 2 °C	---	< 3,5	< 3,5	< 3
Oxygen permeability	ISO 15105-2 DIN 53380-3 ASTM D3985	cm ³ / (m ² · 24h · bar) 50 % r.F. / RH 23 ± 2 °C	---	< 32,5	< 30	< 30
Nitrogen permeability	calculated	cm ³ / (m ² · 24h · bar)	---	< 8	< 7,5	< 7,5
Carbon dioxide permeability	calculated	cm ³ / (m ² · 24h · bar)	---	< 162,5	< 150	< 150
Width	---	mm	± 1			
Length	---	m	± 2 %			



The product meets the legal requirements for food packaging:
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