Declaration of compliance

With the legislation for materials and articles intended to come into

Contact with foodstuffs

We, Dampack International B.V., certify that food packaging films are produced only with components that fulfil the requirements on products, intended for use in direct contact with food, as described in the latest revisions of food contact regulations. Polyolefins are supplied to Dampack International B.V. in compliance with:

EC:
- EC Framework Regulation 178/2002 and 1935/2004 (dated 27-10-2004)
- Plastics Directive 10/2011/EC and amendments
- Regulation 2023/2006 on GMP (dated 29-12-2006)
- FDA rules (21 CFG)

Netherlands:
- Regeling Verpakkingen- en gebruiksartikelen (Warenwet)

German:
- The German Food and Feed Code ((Lebensmittel- Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)), the Consumer Products/Materials Regulation (Bedarfsgegenständeverordnung (BGV))

Additional information
- No products with a functional barrier in a Multi-layer are supplied
- Dual use additives are not used
- All products have to be stored under clean, dry and odourless conditions
- Storage temperature for PS : 5 - 40°C
  for PP : 5 - 40°C
  for PET : 5 - 40°C

We carry out changes in the composition only after consultation with the customers and their written release (clearance) what requires the issuing of an updated declaration of compliance.

References:

Article no Dampack	Article no Supplier	Article description	Certificate no
442617		PP SPG pot 115/138 1000cc TRP	Probe 106 Probe 119

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The supplier shall carefully follow new editions of the relevant laws and shall inform the purchaser of significant changes in the laws and standards which are of importance in connection with the manufacturing and use of the product.
This statement does not apply to a processing which could lead to changes of material characteristics. Tests of the mutual comparability of the material with the food coming into contact and a possible influencing of the organoleptic qualities of the filling stuff is to be carried out by the customer.

1.2 Description of application

Food product	Storage with food contact		Treatmant with food contact		Contact surface to fill quantity ratio [dm^2/kg]
	Tempera-ture (°C)	Storage time (days)	Tempera-ture (°C)	Time (min)	
Dry food	-	-	-	-	-
Watery food	-	-	-	-	-
Sour food	-	-	-	-	-
Dairy products	-	-	-	-	-
fatty foodstuffs	-	-	-	-	-
alcohol-containing foodstuffs	-	-	-	-	-

The temperature and Storage time is based on the standard testing conditions for overall migration with No. OM2 according to VO (EU) 10/2011.

2. Paper/Cardboard packaging

2.1 Paper/Cardboard packaging - general

The paper/cardboard packaging conforms to the recommendation XXXVI – „Paper, cartons and cardboard packaging suitable for contact with foodstuff“ by the Federal Institute for Risk Assessment (BfR) in the respectively valid version. For materials with aluminium foil coating, they conform to DIN EN 602 and FDA 21 CFR 178.3910.

2.2 Paper/ Cardboard packaging in which a plastic-based coating represents the food contact side

☒ Is not applicable as the packaging relates to a non-coated and/or non-laminated paper and/or cardboard packaging and/or the product stated in 1.1 does not fall into this group of products.

In each case, the plastic-based coating which is in direct contact with food in accordance with its intended use, corresponds with the EC Regulation 10/2011, the German Food and Feed Code (Lebensmittel- Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)), the Consumer Products/Materials Regulation (Bedarfsgegenständeverordnung (BGV)) as well as the FDA rules (FDA 21 CFG). We carry out changes in terms of the composition in consultation with and following the written clearance of the client. The issuing of an updated declaration of conformity requires this.

3. Migration and residual contents:

Monitoring of migration and residues is regularly repeated so that the constant agreement with limit values is guaranteed. If migration is at the upper limit, the monitoring is frequently (and instantly) repeated.
The tests are carried out according to Regulation (EU) no. 10/2011
Until 31.12.2015 migration tests can be performed according to Directive 82/711/EEC (amendments 93/8/EEC and 97/48/EC included) and Directive 85/572/EEC (amendment 2007/19/EC included).

3.1 Test conditions for migration tests on the basis of the application

Simulant	Test conditions (time/temperature)	Overall Migration (OM)	application screening tests	Specific Migration
B: Acetic acid 3%	10 days at 40° C	☒	☐	☐
A: Ethanol 10%	10 days at 40° C	☒	☐	☐
D2: 95% Ethanol	10 days at 40° C	☒	☐	☐
B: Acetic acid 3%	10 days at 60° C	☐	☐	☒
D2: 95% Ethanol	10 days at 60° C	☐	☒	☐
-	2 days at 30° C 10 days at 60° C	☐	☐	☒

3.2 Total migration (TM):

The limit value of 60 mg/kg of food or simulant solvent and/or 10 dm^2/kg surface area in the case of containers with a fill quantity of less than 500 ml and/or more than 10 liters or sheets, films and other non-fillable objects is kept below the test conditions cited under 3.1..

3.3 List of evaluated substances with) limitation), d.h. Specific migration limits (SML) and maximum residual contents (QM) and/or(QMA

☐ Is not applicable: materials which are subject to a SML and/or OM and/or QMA value and list *of evaluated substances with) limitations),* are not included.

The SML and/or QM and/or QMA values prescribed in accordance with EC Regulation 10/2011 are kept below the test conditions cited under 3.1.

List of evaluated substances with limitations:

Substance	PM/Ref number	CAS number	SML/QM/QMA [mg/kg]
Test 106:			
Confidential substance A	n/a	n/a	5
Confidential substance B	n/a	n/a	1,2
Confidential substance C	n/a	n/a	0,6

1) "Evaluated substances" are substances which are potentially capable of migration (<1000 daltons) and which were evaluated from a toxicological point of view by an accredited European institution such

as the European Food Safety Authority (EFSA), the Federal Institute for Risk Assessment (BfR) or similar institutions. The materials are hereby suitable for the purposes of Article 1 of Regulation (EC) 1935/2004 to be used in materials and articles intended to come into contact with food. The use restrictions which are connected with the application are observed, such as quantity restrictions, restrictions on migration etc.
Evaluated substances are listed in specific measures in accordance with Article 5 of Regulation (EC) 1935/2004, such as Annex 1 of the plastic Regulation (EU) 10/2011 or in national regulations and recommendations or for the substances exist ratings in the form of statements of accredited institutions.
Evaluated substances are intentionally used in the manufacture and marketing of materials and articles intended to come into contact with food.

3.4 Evaluated Substances according to other provisions

☒ Not applicable, because substances that are not covered by Regulation (EU) No. 10/2011 are not included.

As far as there are evaluated substances (colorants, solvents, production aids, etc.), which are not included in the positive list of Regulation (EU) No. 10/2011, all of them comply with EU Regulations, German laws such as other European and national provisions, recommendations, guidelines etc..

The following substances are concerned:

Substance / constituent	FDA 21 CFR § / Regulation	CAS-No.	Restriction
-	-	-	-

3.5 Non-evaluated substances and functional barrier (FB)

Materials in the scope of Regulation (EU) No. 10/2011: Non-evaluated substances are not carcinogenic, mutagenic or toxic to reproduction (CMR) and only allowed to use behind a functional barrier. The migration of non-evaluated substances which are used behind a functional barrier shall not be detectable (limit of detection < 0,01 mg/kg food). Compliance to chapter 13, paragraph 2, 3 and 4 resp. chapter 14, paragraph 2 and 3 of Regulation (EU) No. 10/2011 is confirmed.
General rule for all materials that are not in scope of Regulation (EU) No. 10/2011: Non-evaluated substances are not carcinogenic, mutagenic or toxic to reproduction (CMR). There should be no detectable migration of non-evaluated substances (limit of detection < 0,01 mg/kg food) respectively a risk-assessment in accordance with internationally recognized scientific principles is available and confirms the compliance with Article 3 of Regulation (EC) No. 1935/2004.
The migration testing of non-evaluated substances is verified with a 10 ppb screening and if necessary with specific determination methods.

3.6 Restricted constituents („dual use additives“)

☐ Not applicable as such substances are not included.
These are:

Substance	PM/Ref number	CAS-No	E-number
test: 119			
Titandioxid	-		
Kohlensäure, Salze			

3.7 Non-intentionally added substances (NIAS)

General rule for all materials: There should be no detectable migration of NIAS (non-intentionally added substances) (limit of detection < 0,01 mg/kg food) respectively a risk-assessment in accordance with internationally recognized scientific principles is available and confirms the compliance with Article 3 of Regulation (EC) No 1935/2004.
The migration testing of NIAS is verified with a 10 ppb screening.

3.8 Undesirable Substances

The use of following materials is excluded on all steps of production process and the materials are not a constitutional component:

☒ Phthalate	☒ Bisphenol S	☒ Toluol	☒ Bisphenol A
☒ Bisphenol F	☒ Benzol	☒ 2-Ethylhexansäure	☒ PVC, PVDC
☒ Ethylenbenzol	☒ Xylol		

4. Glues

☒ Is not applicable

The glues used correspond to the recommendation of the Federal Institute for Risk Assessment (BfR) and/or the FDA rules (FDA 21 CFR Sect.) in their respective current editions.

4.1. Migration Primary Aromatic Amine (PAA)

☒ Is not applicable as no polyurethane glues are used

With the supply, the limit value for the migration of primary aromatic amines is kept in accordance with the official collection of test procedures (in accordance with) Sect. 64 German Food and Feed Code ((Lebensmittel- Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)) Method L.00.006. The migration takes place in accordance with DIN EN 13130-1 with contact surface 2dm^2 wherein the fill quantity is 100 ml. At 70° C, the migration is carried out over 2 hours with 3% acetic acid as a food simulant.

If the detection limit of this method is exceeded, it will be provided evidence, that the specific migration limits concerning primary aromatic amines laid down in the Regulation (EU) No. 10/2011 are met.

5. Print

☒ Is not applicable, unprinted

Printing inks are suitable and approved for printing food packaging in terms of the cited regulations. From this point of view, the raw materials are carefully selected. Direct contact between printing inks and foods is ruled out through the particular printing finish.
The finishes correspond to those stated in the ‘data sheet for printing inks for food packaging’, published by the Printing Ink Industry Association (Verband der Druckfarbenindustrie) and/or ‘exclusion list for printing inks and related products’, published by the European Council of Paint, Printing ink and Artists Colours Industry (CEPE) in their respective current editions.

5.1 Additional information for UV-Printing systems/ UV-Laminating systems

☒ Is not applicable
☐ Cationic hardening system
☐ Radical hardening system
☐ Electron beam curing system

Substances, monomers, residues from photo initiators or benzene, which in a toxicological sense are not exclusively assessed as being harmless, are not traceable in the film of printing ink at a detection limit of 0.01 mg/kg foodstuff. Corresponding test results exist. Assurance is given that the provisions of the Framework Regulation 1935/2004 as well as that of the German Food and Feed Code (Lebensmittel- Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)) are constantly adhered to.
According to good manufacturing practice, the printed materials are manufactured in such a way that they provide, under the specified conditions of use, no ingredients which come from foodstuff in quantities that are likely to harm human health

5.2 Paintings/Coatings (direct contact with food possible)

☒ Is not applicable

The paintings/coatings used correspond to the Council of Europe resolution AP (2004) 1 and/or the FDA rules (FDA 21 CFR).

With regard to migration and residual contents, the points treated under 3 are to be observed.

6. Recycled plastic

☒ Not applicable, recycled plastics according to (EG) No. 282/2008 are not used.

The products comply with regulation (EG) No. 282/2008 (recycling plastics). Recycled material provided by the customer, also cut off of films and set up waste is not considered as usage of recycled plastic.

7. Hygiene

A plan for hygiene, cleaning and combating rodents has been put into place. Upon consultation, it is possible for this to be audited. The manufacturing of packaging materials takes place following the requirements of good hygienic practice, especially techniques for determining potential risks, an assessment of connected risks and a system for controlling recognized dangers (chemical, physical and microbiological risks in accordance with HACCP) for food applications.

☒ A hygiene certificate in accordance with **HACCP** is available
☒ A hygiene certificate in accordance with **BRC/IoP** is available

8. Microbiology

The material is free from pathogenic germs, other germs and mould (<50 KBE/100cm²).

9. Heavy metals

With regard to the contents of heavy metals, the provisions of Directive 94/62 EC (including the amendment Directives 2004/12 EC and 2005/20 EC) are adhered to.

10. Powders

Powders are not used.

11. Reach VO

Delivered materials and products correspond to the demand of the order (EC) Nr. 1907/2006.
It is ensured that no substances that are a cause for concern are contained for the purpose of Act (EC) No. 1907/2006. The basis for this is the “Candidate List of Substances of Very High Concern” (SVHC list) which is currently valid.

12. Supporting documents

OM-test-report: 106
Screening-test-report: 106,
Specific migration-test-report: 106,

Other documents**:** „Konformitätserklärung Masterbatch (Probe 119)“

It should be noted that the product has been tested for the abovementioned forms of usage and conditions. Therefore, it will be the sole responsibility of the downstream users to determine that the usage of the product complies with the information given in this document and is safe, lawful and technically suitable so that no change in flavour, taste or organoleptic properties occurs. In case the product will be used in a different manner than tested, the information in this declaration of compliance will not apply and the downstream users shall be responsible for the compliance with the legislation and regulations.

Werkendam,

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