

FORUM-PLAST GmbH	Declaration of conformity for primary and secondary packaging of food	10 / 2021
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1. General

1.1 Address of the manufacturer:

Forum-Plast GmbH
Wernher-von-Braun Str. 20
D-92224 Amberg

1.2 This declaration of conformity is issued to the customer:

Antalis A/S
Bastrupgaardvej 8 – 10
DK-7500 Holstebro

1.3 This declaration of conformity shall be valid for:

- 1321106 Plastic hood LDPE transparent 1200/450x700x0,025mm
- 1321110 Plastic hood LDPE transparent 1200/450x1500x0,025mm
- 1321121 Plastic hood LDPE transparent 1200/450x1800x0,025mm
- 1321132 Plastic hood LDPE transparent 860/315x1500x0,025mm

The above-mentioned article complies with the EC-Framework Regulation 1935/2004, the EU-Regulation (PIM) No. 10/2011 (last amended on 02.09.2020 with the regulation 2020/1245), the FDA regulations (FDA 21 CFR) and the FDA regulations (FDA 21 CFR) and the GMP Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Note:

Food may only be packaged in such a way that the ink is on the side opposite the food (also applies to material labelling 02 HDPE, 04 LDPE.) We recommend not to use material labelling.

No measurement of the transition of substances from the printed to the food side (by clamping) has been carried out.

2. Migration and residues

Checks on migration and residual levels are regularly repeated to ensure compliance with the limit values. The tests shall be carried out in accordance with articles 17 and 18 of Regulation (EU) No. 10 / 2011 in conjunction with annex V.

2.1 Tested application conditions:

Overall migration analysis on the finished product is conducted as per EC-Reg 10/2011 simulant B (acetic acid 3%) and D (olive oil or ethanol 95% + isooctane).

Test conditions: the migration test was carried out by putting the food contact side in direct contact with the simulant under the following conditions:

contact time = 10days /Temperature=40°C.

2.2 Overall Migration

The overall migration result is below the law limit = 60mg/kg, according to EC-Reg 10/2011

Note:

Due to the number of articles and productions, migration measurements of the total migration are carried out at regular intervals using the worst-case procedure.

Last test performed in January 2020.

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2.3 Application description according to Regulation EU No. 10 / 2011, Annex V.

Types of food

- All kinds of food

Intended food contact conditions

- Any food contact under freezing conditions and cooling conditions

Any long-term storage at room temperature or below, including heating to 70 for up to 2 hours or heating to 100 for up to 15 Minutes.

2.4 Specific migration limits / or Dual Use Additive

In the manufacture of the granules used for our products, substances with restrictions (SML or QM values) and / or dual use additives are used.

Compliance with the limit values is confirmed for the specified food types and conditions of use.

These statements are based on documentation from the issuer of the declaration of conformity (supporting documents).

These documents may contain the following substances in our products (indication of raw material suppliers).

According to the information provided by our raw material suppliers, the following substances may be contained in our products (information provided by the raw material suppliers)

FCM-Nr.	Ref.-Nr.	CAS-Nr.	E-Nr.	Substance name	Limit
19	39090	108-78-1	----	N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)amin	1,2 mg/kg
222	13870	0000106-98-9	----	1-Buten	---
264	22660	0000111-66-0	----	1-Octen	15 mg/kg
356	18820	0000592-41-6	----	1-Hexen	3 mg/kg
433	68320	0002082-79-3	----	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionat	6 mg/kg
652	38820	0026741-53-7	----	Bis(2,4-di-tert-butylphenyl) pentaerythritoldiphosphit	0,6 mg/kg
	Annex II			Zinc	5 mg/kg
21	42500	-----	E170	Carbonic acid,	---
106	89040	0000057-11-4	E570	Stearic acid	---
504	86240	0007631-86-9	E551	Silicon dioxide	---
610	93440	0013463-67-7	E171	Titanium dioxide	---
615	92080	0014807-96-6	E553b	Talc	---
638	23590	0025322-68-3	E1521	Polyethylene glycol	---
			E470a		---
			E572	Magnesium stearate	---

2.5 General information about the raw materials

For primary food packaging, Forum-Plast only uses raw materials and additives for which we have the necessary food safety declarations in accordance with current legislation.

No functional barrier made of plastic is used.

3. Adhesives

No adhesives, including polyurethane adhesives, containing aromatic amines are used

4. Lacquering / Coating / Printing

N/A

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5. Hygiene

The production of packaging materials is carried out under the conditions of good hygienic practice.

6. Heavy metals

The elements lead, cadmium, mercury and chromium (IV) are not constitutional components of our products.

According to CONEG or EU Directive 94/62 EEC, the total heavy metal content of the elements mentioned is < 100 ppm.

7. Powder

Powder are not used.

8. Reach VO / SVHC Substances

The products supplied by us comply with the requirements of Regulation (EC) No. 1907 / 2006.

Assurance is given that no substances of very high concern within the meaning of Regulation (EC) No. 1907 / 2006 are contained. The basis is the respectively valid, candidate list of Substances of very high Concern.

The products can consist of both mono-layer and multi-layer formulations (polyethylene).

9. NIAS

According to recitals 18 und 20 of the European Plastics Regulation (EU) No. 10 / 2011 our PE-Films are tested for the presence and health risk of the non-intentionally added substances. (NIAS)

If NIAS are found, their harmlessness to human health is clarified, e. g. by means of a toxicological risk assessment.

10. Disclaimer

A concrete risk assessment can only be made by case-by-case examination, i.e., packaged food including storage conditions and shelf-life periods.

The testing and suitability of the packaging material for the intended use is the responsible for ensuring that the relevant migration limits in the food itself are complied with under the conditions actually applied.

Forum-Plast GmbH is not responsible for changes in the quality of the food due to unknown or improper use of the products.

This declaration corresponds to the current status known to us and only applies to the above-mentioned customer for the material supplied by us directly to him.

It refers to the raw material composition of the product and not to pallets, sleeves and transport packaging.