Issue date 27.9.2023

DECLARATION OF COMPLIANCE

Product reference: **OPALEN (HB)**

as supplied by: AMCOR FLEXIBLES VALKEAKOSKI OY
Niementie 161; FI-37601 Valkeakoski, Finland

This product is composed of the following components:

table 1 – product composition (from the external layer to the internal layer).

45-90 µ	OPA15-20 µ / PE 30-70 µ coextruded film; HB with EVOH; AF with antifog; UV with UV barrier; different sealants; PEEL, EZP as peelable, PET and PP sealable versions - Not all thickness/material combinations available

The exact nature of the components used is Amcor Flexibles Valkeakoski proprietary information. Details of the formulation could be supplied to an independent third party under secrecy agreement.

1. Compliance with food contact legislation.

This product complies with Regulation (EC) No 1935/2004. In particular, it is manufactured under good manufacturing practices, from components and ingredients which are declared suitable for food contact use, and is therefore considered to comply with the general safety requirements (Art. 3). We also comply with Art. 11(5), the provisions on labelling (Art. 15), declaration of compliance (Art. 16) and traceability (Art. 17). See below for details on the conditions of use.

Our good manufacturing practices meet the requirements of Regulation (EC) No 2023/2006 and follow relevant sections of the "Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food" issued by Flexible Packaging Europe (http://www.flexpack-europe.org/).

The following table lists the regulatory status of the components used in manufacturing our product:

table 2 – regulatory status of product components.

Component	Legal Reference	Status(**)
plastics	Regulation (EU) No 10/2011 (*)	monomers & additives listed; see below for further compliance aspects.
plastic functional barrier	Regulation (EU) No 10/2011 (*), Art. 13(2) and 14(2).	monomers & additives not listed in the Union List are not used in a plastic layer of our product.
vinyl chloride monomer	Directive 78/142/EEC	VCM is not used.
recycled plastics	Regulation (EC) No 2022/1616	mechanically recycled PCR plastics are not used.
active & intelligent	Regulation (EC) No 450/2009	A&I are not used.
Bisphenol A	Regulation (EU) 2018/213	BPA is not used.
epoxy derivatives	Regulation (EC) No 1895/2005	epoxy not used.
nanomaterials	Recommendation 2011/696/EU	nanomaterials are not used.
biocides	Regulation (EU) No. 528/2012	biocides are not used.

printing inks	n.a.	comply with EuPIA exclusion policy.

(*) Regulation (EU) No 10/2011 was amended by Regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/1338 and 2020/1245, 2023/1442 and 2023/1627. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

(**) The term "used" refers to intentional presence in our raw materials or added during manufacturing. We cannot exclude trace impurities or incidental contaminants.

2. Further details on EU food contact compliance.

2a. Conditions of use

Taking into account the relevant legal provisions as well as the formulation of our raw materials and the OML and SML compliance information reported below, we can give clearance for the use of our product in contact with food in the following conditions of use:

- single use applications only
- intended food contact side (see layer sequence in Table 1): internal side (PE / PP / PET) .
- food types: all foods.
- packed food storage conditions: indefinite storage time, up to room temperature (including freezing; note – surface printing inks adhesion may suffer in freezing).
- in-pack processing: heating up to 85°C (guidance only) without defined time limitation (see point 2c.)

These conditions of use may include microwave re-heating on provision that the conditions inside the package, to be verified by the customer, do not exceed the time and temperature listed.

The highest surface to volume ratio for which the compliance of this product has been assessed, is 6 dm^2/kg. Article 17 of Regulation (EU) No 10/2011 provides that for sheet and film not yet in contact with food, the value of specific migration is expressed in mg/kg by applying the conventional surface to volume ratio of 6 dm^2/kg.

2b. Overall Migration Limit

Our product is a plastic as defined in the scope of Regulation (EU) No 10/2011, and therefore subject to an Overall Migration Limit (OML) of 10 mg/dm^2 as laid down in Article 12 of the Regulation.

In testing for verification of the OML we follow the methods that have been laid down in the EN 1186 series of standards by CEN.

2c. OML test conditions

The overall migration, when tested on relevant samples (this product or one of similar composition), was found to comply with the OML in the following test conditions:

- OM2 (10 days at 40°C) + OM5 (2 hours at 100°C or at reflux) in simulants A, B.
- OM5 (2 hours at 100°C or at reflux) in simulant D2 (or substitutes).

The test results, obtained on a relevant sample (this product or one of similar composition) in the conditions listed, are as follows:

table 3 – OML test results.

simulant	test condition	result (mg/dm^2)
simulant A (10% ethanol)	OM2 + OM5	< 3
simulant B (3% acetic acid)	OM2 + OM5	< 3
simulant D2 (vegetable oil / substitutes)	OM5	< 6

Notes:

- Simulant E (Tenax) or 100% ethanol is intended for SML testing. (or screening)
- According to section 4 of Annex III of the Regulation, for OML testing the combination of simulants A, B and D2 allows to conclude on compliance for all types of foods.

- According to Chapter 3 of Annex V of the Regulation, OML test condition OM5 represents the worst case test condition for materials having a polyolefin (PE, PP) food contact layer. Polyolefin-based materials passing this test are considered sufficiently inert even if the time/temperature conditions in actual use exceed the test condition.

These OML test results have been taken into account in the conditions of use reported in section 2a.

2d. Specific restrictions on substances in plastics.

Our product contains one or more plastic components regulated by Regulation (EU) No 10/2011. This Regulation provides specific restrictions on monomers, starting substances and additives used in the manufacturing of plastics.

Some or all of the restricted substances listed in table 4 may be present in the finished material:

table 4 – specific restrictions on substances in Annex I of Regulation (EU) No 10/2011.

No.	PM ref.	Substance name	CAS Nr.	Restriction (**)	Status (table 5)
00231	10120	acetic acid, vinyl ester	108-05-4	SML = 12 mg/kg	5
00176	11710	acrylic acid, methyl ester	96-33-3	SML (T) = 6 mg/kg	3
00212	14200	caprolactam	105-60-2	SML(T) = 15 mg/kg	5, 7
00263	15760	diethylene glycol	111-46-6	SML(T) = 30 mg/kg	5
00227	16990	ethylene glycol	107-21-1	SML(T) = 30 mg/kg	5
00356	18820	1-hexene	592-41-6	SML = 3 mg/kg	3, 5
00234	19960	maleic anhydride	108-31-6	SML(T) = 30 mg/kg (maleic acid)	5, 7
00264	22660	1-octene	111-66-0	SML = 15 mg/kg	3, 5
00785	24910	terephthalic acid	100-21-0	SML(T) = 7.5 mg/kg	5
00584	40320	boric acid	10043-35-3	SML(T) = 6 mg/kg (Boron)	5
00315	46640	2,6-di-tert-butyl-p-cresol = 3,5-di-tert-butyl-4-hydroxytoluene (=BHT)	128-37-0	SML = 3 mg/kg	3, 7
00433	68320	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	SML = 6 mg/kg	3, 5, 7
00974	74050	phosphorous acid, mixed 2,4-bis(1,1- dimethylpropyl)phenyl and 4-(1,1- dimethylpropyl)phenyl triesters	939402-02-5	SML(T) = 5 mg/kg ; SML = 1 mg/kg for 2,4-di-tert-amylphenol	3
00106	89040	stearic acid (#)	557-05-1	SML(T) = 5 mg/kg (Zinc)	3
00402	96240	zinc oxide	1314-13-2	SML(T) = 5 mg/kg (Zinc)	3
		undisclosed aluminium compound(s)		SML(T) = 1 mg/kg (Aluminium)	5
		proprietary substance(s)		not known	5

(**) Restrictions can be a specific migration limit (SML), a maximum concentration (QM) in the plastic, a maximum quantity per surface area (QMA), or a 'no detectable migration' (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

(#) The substance used is a salt of an authorised acid; the Substance No., PM Ref nr. and substance name refer to the authorised acid; the CAS nr. and restriction refer to the salt.

The above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers. The status with regard to the latest amendments of Regulation 10/2011 is as follows:

- Amendments up to 2020/1245 : fully covered by Table 4.
- Amendment 2023/1442: not yet covered by Table 4. Note that our product is a finished FCM; a transition period until 1 Feb. 2025 applies.
- Amendment 2023/1627 : fully covered by Table 4.

2e. Compliance with specific restrictions on substances in Table 4

The specific restrictions on substances listed in Table 4, apply to our product and/or its plastic components. Our compliance assessment as summarized below is carried out on the basis of the surface/volume ratio reported in section 2a above. The results of this compliance assessment have been taken into account in the conditions of use reported in section 2a.

table 5 – compliance assessment for substances listed in table 4.

Status (table 4)	compliance status
3	cannot exceed the limit even if total quantity migrates
5	compliance is confirmed by our supplier
7	GC-MS / GC-FID screening shows substance migration is well below the limit (***)

(***) results obtained on sample(s) relevant for this specific restriction.

2f. Compliance with Annex II of Regulation 10/2011.

On the basis of information currently available to us, the compliance of our product with the substances listed in Table 1 of Annex II is ensured as follows:

- Substances of Annex II.1 that are disclosed by our suppliers as being used in our raw materials, are addressed in table 4 of this document.
- Substances of Annex II.1 that arise from impurities in our raw materials are covered by our suppliers' statements of compliance with Article 19 of Regulation 10/2011 and/or Article 3 of Framework Regulation 1935/2004, or a specific supplier statement of compliance with Annex II.1.

The compliance of our product with the provisions on Primary Aromatic Amines (PAA), if relevant for our product, is addressed in tables 4 and 5 of this document. In accordance with the recommendations of FEICA, we use a detection limit of 0.002 mg/kg food or food simulant for all PAA species.

2g. Dual Use Additives

As required by Regulation (EU) No 10/2011 the following table identifies substances used in plastics and subject to a restriction in food through an authorisation as food additive. In absence of a Union reference list of these substances, or a marking in the Regulation, there remains some uncertainty over precisely which additives are to be considered as dual use additives. Therefore the following information received from our suppliers could be considered preliminary:

table 6 – dual use additives.

food additive	substance
E284	boric acid
E307	alpha-tocopherol
E321	3,5-di-tert-butyl-4-hydroxytoluene
E330	citric acid
E338	phosphoric acid
E471	mono- and diglycerides of fatty acids
E475	polyglycerol esters of fatty acids
E551	silicon dioxide
E1521	polyethylene glycol

3. Additional information on substances.

The information in this section is to the best of our knowledge and is based on information received from our raw material suppliers, which may be incomplete, or on spot testing. As such, incomplete or inaccurate information given here cannot be the cause of any claim or rejection or other liability inferred upon us.

3a. Substances for which genotoxicity has not been ruled out.

Amendment 2020/1245 requires a flow of information in the supply chain on the potential presence of substances for which genotoxicity has not been ruled out according to the rules of the EFSA risk assessment methodology.

Should any of our suppliers disclose the presence of such substances for which genotoxicity has not been ruled out, this paragraph will be updated with any information that may be needed for a final risk assessment when this hasn't already been conclusive at our stage or upstream.

3b. Non-Intentionally Added Substances (NIAS).

Our suppliers have either explicitly confirmed that a risk assessment according to Article 19 of Regulation 10/2011 has been carried out, or have implicitly done so by confirming compliance with Regulation 1935/2004. Information on our assessment of NIAS is part of our supporting documentation and is available to the authorities on their request.

4. Environmental Compliance

Our product is manufactured in compliance with Directive 94/62/EC on Packaging and Packaging Waste, as amended. More specifically, the combined total amount of Lead, Cadmium, Mercury and hexavalent Chromium in above-mentioned material does not exceed 100 ppm.

In addition we can confirm that our product is made of plastics which, according to Annex B of EN standard 13431:2004 provide a positive calorific gain upon incineration.

With regard to the requirement on source reduction we point to Table 2 of EN 13427:2004 where it is explained that this assessment needs to be made at the level of the complete packaging system i.e. primary + secondary + tertiary packaging; consequently it is out of our control.

5. BSE/TSE

Throughout the plastics converting industry, certain low-level additives which are based on fatty acids, fatty acid esters or glycerol that are derived from animal fats (tallow) are in widespread use; the use of these additives is generally considered to be unavoidable in many different types of plastics. Tallow itself is not used in our products.
However, it has to be pointed out that:

- these substances are approved for food-contact use.
- Regulation (EC) No 999/2001 and its amendments assure that Specified Risk Materials (SRM) are removed prior to production of the materials of animal origin from which the above-mentioned substances are derived.
- the production of these additives is subject to very severe processing conditions that meet or exceed the recommendations for complete inactivation of TSE agents.

We therefore are certain that no danger for human health can result from the use of the above-mentioned additives and, by extension, our product.

6. Absence of chemical substances

Based on the information available to us, the following substances are not intentionally used in our raw materials nor added during manufacturing. Therefore our product is not expected to contain:

- acrylamide
- allergens listed in Annex II of Regulation (EU) No 1169/2011 as amended
- azodicarbonamide and semicarbazide
- asbestos
- brominated flame retardants
- substances intended to function as biocides and fungicides incl. dimethyl fumarate, paraben.
- Bisphenol A, Bisphenol S
- Bisphenol A Diglycidyl Ether (BADGE), Bisphenol F Diglycidyl Ether (BFDGE) or Novolac Glycidyl Ethers (NOGE)
- dioxins
- genetically modified organisms (GMO) or products containing GMO
- mineral oil solvents not listed in Reg. 10/2011, other mineral oil saturated hydrocarbons (MOSH), mineral oil aromatic hydrocarbons (MOAH)
- natural rubber or natural rubber latex
- nonylphenol or nonylphenol ethoxylate
- oxo-degradable substances or substances making our product oxo-degradable
- ozone depleting substances according to the Montreal Protocol
- PFAS including fluoropolymers, perfluoro-octanoic acid (PFOA), perfluoro-nonanoic acid (PFNA), perfluoro-hexane sulfonic acid (PFHxS), perfluoro-octane sulfonic acid (PFOS), perfluoro-alkyl

phosphate esters (PAPs), perfluoro-alkyl carboxylic acids (PFCAs) and other perfluoro-alkyl acids (PFAA).
- photo-initiators, including benzophenone, benzophenone derivatives, isopropyl thioxanthone (ITX), etc.
- phthalate plasticizers
- polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)
- polychlorinated biphenyls (PCB)
- polycyclic aromatic hydrocarbons (PAH)
- post-consumer recycled waste
- PVC or PVDC
- titanium acetyl acetonate (TAA) or acetyl acetone
- triclosan
- UV-curing components

The absence of these substances has not been confirmed by testing. We cannot exclude trace impurities at insignificant levels resulting from incidental contamination or from impurities in precursors to our raw materials.

7. Other information / standards

Amcor Flexibles Valkeakoski Oy is certified for ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, and BRC (Global Standard for Packaging Materials – Issue 6: August 2019).

8. Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It only covers the food contact compliance status of our product as it leaves our premises and does not imply any conclusions regarding technical aspects of the use of our product nor any unforeseen interactions of our product with the packaging process or the filling good.

This declaration replaces all previous declarations for the same specification/product. It remains valid until a change in the legislation or new scientific information change the legal status.

Hanna Lahti
Compliance manager
(valid without signature)

Vaatimuksenmukaisuustodistus koskee seuraavia Ki-Sal Oy:n maahantuomia ja myymiä tuotteita:

Ki-Sal tuotekoodi	**Tuotekuvaus ja toimittajan tuotenumero**
WIKK190/250	Kansikalvo OPALEN 65 AF PP 190mm/200m höyrystymätön

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