DECLARATION OF COMPLIANCE

Product reference: ***Flexalcon Base***

Identifier: FXU001, SMAT 3019409, TDSF0030-E

as supplied by: AMCOR FLEXIBLES Singen GmbH
Alusingen-Platz 1, 78224 Singen, Germany

for application: Base material for retortable, coldformable laminate

This product is composed of the following components:

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

30 µ	Polypropylene film
4 g/m^2	Adhesive (Polyurethane)
1,6 g/m^2	Primer (Polyurethane)
45 µ	Aluminium foil
4 g/m^2	Adhesive (Polyurethane)
15 µ	Polyamide film
4 g/m^2	Adhesive (Polyurethane)
75 µ	Polypropylene film

The exact nature of the components used is Amcor Flexibles Singen 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
Polypropylene films	Regulation (EU) No 10/2011 (*)	monomers & additives listed; see below for further compliance aspects.
Polypropylene films	FDA 21 CFR section 177.1520; 177.1390	compositional compliance.
Adhesive layers	Regulation (EU) No 10/2011 (*)	compositional compliance
Adhesive layers	FDA 21 CFR 175.105; 177.1390	compositional compliance
Polyamide film	Regulation (EU) No 10/2011 (*)	monomers & additives listed; see below for further compliance aspects.
Polyamide film	FDA 21 CFR section 177.1500	compositional compliance.
vinyl chloride monomer	Directive 78/142/EEC	VCM is not used.

recycled plastics	Regulation (EC) No 282/2008	recycled 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 not used.
aluminium foil	Regulation (EC) No 1935/2004	complies.
aluminium foil	n.a.	complies with EN 602.

(*) Regulation (EU) No 10/2011 replaces Directive 2002/72/EC since 1 May 2011. It was amended by Regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213 and 2018/831. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

table 2.a – surface lubricants used in our product:

Inside Layer/Component	FDA 21 CFR §	Status
aluminium foil	21 CFR 178.3910	complies

2. Further details on EU food contact compliance.

a. 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, or it is a multi-material multilayer as defined in the Regulation for which we nonetheless consider the OML relevant.

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.

b. Migration test conditions and conditions of use

The overall migration was tested on relevant samples by our film supplier, and was found to comply with the OML in the following test conditions:
The overall migration, when tested on relevant samples, was found to comply with the OML in the following test conditions:

- 0,5 h 121°C + 10 d 40°C in distilled water
- 0,5 h 121°C + 10 d 40°C in simulant B
- 1,5 h 60°C+ 2 d 20°C in isooctane
- 2 h 121 °C in distilled water (conditions of 21 CFR 177.1390)

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)
Distilled water	*0,5 h 121°C + 10 d 40°C*	*< 2*
simulant B (3% acetic acid)	*0,5 h 121°C + 10 d 40°C*	*< 2*
iso-octane (sim. D2 substitute)	*1,5 h 60°C+ 2 d 20°C*	*< 4*
Distilled water	*2 h 121 °C*	*< 2*

Taking into account the relevant legal provisions as well as the formulation of our raw materials and the 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:

- food types: Dry, moist, liquid, liquid acidic and fatty food .
- packed food storage conditions: indefinite storage time, up to room temperature.
- in-pack processing: heating up to 121°C for up to 2 hours.

The conditions of use reported above take into consideration the restrictions (if any) that follow from the SML compliance assessment reported in Table 5.

c. 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 plastics under Regulation (EU) No 10/2011, food contact layer.

No.	PM ref.	Substance name	CAS Nr.	Restriction (**)	Status (table 5)
00212	14200 41840	caprolactam	105-60-2	SML (T)= 15 mg/kg	5
00263	15760	diethylene glycol	111-46-6	SML(T) = 30 mg/kg	2
00227	16990	ethylene glycol	107-21-1	SML(T) = 30 mg/kg	2/8
00291	19150	isophthalic acid	121-91-5	SML(T) = 5 mg/kg	8
00141	25600	1,1,1-trimethylol propane	77-99-6	SML = 6 mg/kg	9
00019	39090	N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine	-	SML(T) = 1,2 mg/kg	9
01068	-	[3-(2,3-epoxypropoxy) propyl]trimethoxy silane	2530-83-8	SML(T) = ND; DL = 0.01 mg/kg	8
-	-	isocyanate	-	SML(T) = ND; DL = 0.01 mg/kg QM = 1 mg/kg (free NCSML = 6mg/kg O)	10
-	-	phthalic acid, alkyl esters (unspecified)	-	lowest: QM = 0.05% / SML = 0.3 mg/kg	2
-	-	undisclosed aluminium compound(s)	-	SML(T) = 1 mg/kg (Aluminium)	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 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 2018/79 : fully covered by Table 4.
- Amendment 2018/213 : fully covered by Table 4.
- Amendment 2018/831 : partly by Table 4 – note that there is a transition period until 26 June 2019 for this to be implemented.

d. Compliance with specific restrictions on substances

The specific restrictions on substances listed in Table 4, apply to our product and/or its plastic components. In assessing compliance with these restrictions, it has to be noted that Article 17 of Regulation (EU) No 10/2011 provides that for sheet and film not yet in contact with food, the value of migration is expressed in mg/kg by applying the conventional surface to volume ratio of 6 dm^2/kg. This applies also to the finished food package if it contains less than 500 ml or more than 10 l.

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

Status (table 4)	compliance status
1	no information
2	complies based on OML test results (***)

3	cannot exceed the limit even if total quantity migrates
4	compliance was verified by validated migration modelling
5	compliance is confirmed by our supplier
6	GC-MS / GC-FID screening shows substance is not detected/identified at 10 ppb (***)
7	GC-MS / GC-FID screening shows substance migration is well below the limit (***)
8	compliance was confirmed by specific test for this substance (***)
9	to be confirmed by specific migration testing
10	finished product complies when the curing is complete

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

Contact us for more details on this compliance assessment if needed.

e. 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
E470a	calcium stearate
E471	mono- and diglycerides of fatty acids
E530	magnesium oxide
E551	silicon dioxide

3. Non-listed or non-intentionally added substances

Our suppliers have either explicitly confirmed that a risk assessment 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, paper and 'combustible' aluminium which, according to Annex B of EN standard 13431:2004 provide a positive calorific gain upon incineration.

When used by itself, our product meets the requirements of EN 13430:2004 on packaging recoverable by material recycling, on condition that it is verified to fulfil all relevant local regulations and provided that appropriate facilities exist where the packed product is put on the market.

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/esters/alcohols 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.
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. Based on the above, we furthermore declare our products compliant with

Section 6.4 "Tallow derivatives" of the "Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products." (EMEA/410/01 Rev. 3 – 2011).

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
- ozone depleting substances according to the Montreal Protocol
- perfluoro-octanoic acid (PFOA), perfluoro-octane sulfonate (PFOS), perfluoro-alkyl phosphate esters (PAPs), perfluorinated carboxylic acids (PFCAs)
- 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. Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It covers the composition of the above-mentioned material and does not imply technical suitability of our product in its intended use. Appropriate filling and storage tests remain necessary. This declaration may become invalid when our product is not properly processed or when it is altered by thermal or other degradation processes.

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. At such time we will inform our customers accordingly.

The food packer is responsible for ensuring that the finished food package complies with applicable restrictions in the food itself under actual conditions of use. Possible interactions of the film and its components with the foodstuff (i.e. modification of odour, taste, consistency, migration, etc.) are to be checked prior to use and in function of the end-uses.

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