

DECLARATION OF COMPLIANCE

Product reference: Aluthene IVE110/21 12PET 12IVE110/21
as supplied by: Amcor Flexibles Sélestat
2 Rue Frédéric Meyer, BP 128 67600 Sélestat

to customer: LABLABO
for application: Dry Pharmaceutical Products
customer reference:

This product is composed of the following components:

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

Aufbau / Composition	Dicke / Thickness [µm]	Grammatur / Unit mass [g/m²]	Dichte / Density [g/cm³]
Extrusion coating		50	0.923
primer 2K		1	1.021
Film PET	12	16.74	1.395
adhesive		3	1.047
Aluminium foil (barrier layer)	12		2.71
Extrusion coating		50	0.923

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

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.

85656009; 85680509; 85680502; 85693597	date: 10.Nov 2021	1/7
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Layer	Component	Legal Provisions (recommendations, codes, decrees) for plastics, aluminium, paper / board, coatings and other components
Extrusion coating		Regulation (EU) No 10/2011 Regulation (EC) No 1935/2004 Pharmacopeia European Pharmacopoeia 8th Ed. - Chapter 3.1
primer 2K		Regulation (EC) No 1935/2004 Regulation (EC) No 2023/2006 Regulation (EC) No 1895/2005 Directive 94/62/EC Directive 94/62/EC amended up to 2015/720/EU Directive 2011/65/EU DIRECTIVE 2015/863 Guideline FEICA Guide FCM (2014) Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245
Film PET		Regulation (EC) No 1935/2004 Regulation (EU) No 10/2011 Directive 94/62/EC Regulation (EC) No 2023/2006 Directive 94/62/EC amended up to 2018/852/EU Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245
adhesive		Regulation (EC) No 1935/2004 Regulation (EC) No 2023/2006 Regulation (EC) No 1895/2005 Directive 94/62/EC Directive 94/62/EC amended up to 2015/720/EU Directive 2011/65/EU DIRECTIVE 2015/863 Guideline FEICA Guide FCM (2014) Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245
Aluminium foil (barrier layer)		Regulation (EC) No 1935/2004 Regulation (EC) No 2023/2006 Directive 94/62/EC Standard EN 602 Standard EN 573-3
Extrusion coating		Regulation (EU) No 10/2011 Regulation (EC) No 1935/2004 Pharmacopeia European Pharmacopoeia 8th Ed. - Chapter 3.1

(*) Regulation (EU) No 10/2011 replaces Directive 2002/72/EC from 1 May 2011. It was amended by Regulation 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37 and 2019/1338. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

Further details on EU food contact compliance

Overall Migration Limit

Our product is not a plastic as defined in Regulation (EU) No 10/2011, nor a plastic-coated regenerated cellulose film as defined in Directive 2007/42/EC. Therefore the Overall Migration Limit (OML) of 10 mg/dm² as laid down in Regulation (EU) No 10/2011, does not apply to this product.

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.

FCM no	Name EU	n° CAS	Restriction	validation by
264	1-OCTENE	0000111-66-0	SML 15 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245	GC-MS / GC-FID screening shows substance is not detected/identified at 10 ppb (***)
315	2,6-DI-tert-BUTYL-p-CRESOL (BHT)	0000128-37-0	QMA 0.06 mg/dm ² Directive 2007/42/EC SML 3 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 SML 3 mg/kg Resolution ResAP (2005) 2 Version 2 Regulation (EC) 1333/2008 amended up to (EU) 2021/1175	cannot exceed the limit even if total quantity migrates
377	3-AMINOPROPYLTRIETH OXYSILANE	0000919-30-2	DL 0.01 mg/kg Resolution Policy Silicones 2004 V.1 SML 0.05 mg/kg QM 3 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57	compliance is confirmed by our supplier
398	ANTIMONY TRIOXIDE	0001309-64-4	SML 0.04 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57	compliance is confirmed by our supplier
501	Aluminium (Al), incl. fibres, flakes and powders	0007429-90-5	SML 5 mg/kg Resolution CM/Res(2013)9 Resolution Policy Silicones 2004 V.1 SML 1 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57 Resolution ResAP (2005) 2 Version 2 Regulation (EC) 1333/2008 amended up to (EU) 2021/1175	compliance is confirmed by our supplier
715	CALCIUM BIS(3,5-DI-tert-BUTYL-4-HYDROXYBENZYL-MONOETHYL)PHOSPHONATE	0065140-91-2	SML 6 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245	cannot exceed the limit even if total quantity migrates
490	DIPHENYLMETHANE-2,4'-DIISOCYANATE	0005873-54-1	QM 1 mg/kg DL 0.01 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57	finished product complies when the curing is complete
198	DIPHENYLMETHANE-4,4'-DIISOCYANATE	0000101-68-8	QM 1 mg/kg DL 0.01 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57 DL 0.01 mg/kg Resolution ResAP (2005) 2 Version 2	finished product complies when the curing is complete

FCM no	Name EU	n° CAS	Restriction	validation by
263	Diethyleneglycol	0000111-46-6	QM 270000 mg/kg Directive 2007/42/EC SML 30 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57 Resolution ResAP (2005) 2 Version 2	finished product complies when the curing is complete
227	Ethylene glycol	0000107-21-1	QM 270000 mg/kg Directive 2007/42/EC SML 30 mg/kg Resolution Policy Silicones 2004 V.1 SML 30 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57 Resolution ResAP (2005) 2 Version 2	finished product complies when the curing is complete
372	HEXAMETHYLENE DIISOCYANATE	0000822-06-0	QM 1 mg/kg DL 0.01 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57	finished product complies when the curing is complete
291	ISOPHTHALIC ACID	0000121-91-5	SML 5 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 SML 5 mg/kg Resolution ResAP (2005) 2 Version 2	compliance is confirmed by our supplier
150	METHACRYLIC ACID	0000079-41-4	SML 6 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 Regulation (EC) No 1907/2006 amended to (EU) 2021/57 Resolution ResAP (2005) 2 Version 2	cannot exceed the limit even if total quantity migrates
433	OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE	0002082-79-3	SML 6 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245	GC-MS / GC-FID screening shows substance migration is well below the limit (***)
785	TEREPHTHALIC ACID	0000100-21-0	SML 7.5 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2020/1245 SML 7.5 mg/kg Resolution ResAP (2005) 2 Version 2	compliance is confirmed by our supplier
	Zinc (Zn)	0007440-66-6	SML 5 mg/kg Resolution CM/Res(2013)9 Regulation (EC) No 1907/2006 amended to (EU) 2021/57	compliance is confirmed by our supplier

(**) 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.

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

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 migration limits expressed in mg/kg are expressed in mg/dm² units after division by the conventional conversion factor of 6 dm²/kg. This applies also to the finished food package if it contains less than 500 ml or more than 10 l.

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:

table 6 – dual use additives.

E number	Name EU
E 321	2,6-DI-tert-BUTYL-p-CRESOL (BHT)
E 260	ACETIC ACID
E 173	Aluminium (Al), incl. fibres, flakes and powders
E 551	SILICON DIOXIDE

Additional information on substances

The information in this section falls outside the scope of the legal requirements on information flow on food contact compliance (Annex IV of Regulation 10/2011). This information is considered strictly confidential and may only be used for purposes of regulatory assessments. The information 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.

List of Components (LoC)

To the best of our current knowledge the above information on substances is complete. Therefore a separate LoC is not required.

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.

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.

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).

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:

Substance	Not constitutional component
acrylamide	Yes
allergens listed in Annex II of Regulation (EU) No 1169/2011 as amended	Yes
asbestos	Yes
azodicarbonamide and semicarbazide	Yes
biocides and fungicides incl. dimethyl fumarate, paraben	Yes
Bisphenol A Diglycidyl Ether (BADGE), Bisphenol F Diglycidyl Ether (BFDGE) or Novolac Glycidyl Ethers (NOGE)	Yes
Bisphenol A, Bisphenol S	Yes
brominated flame retardants	Yes
dioxins	Yes
genetically modified organisms (GMO) or products containing GMO	Yes
mineral oil solvents not listed in Reg. 10/2011, other mineral oil saturated hydrocarbons (MOSH), mineral oil aromatic hydrocarbons (MOAH)	Yes
natural rubber or natural rubber latex	Yes
nonylphenol or nonylphenol ethoxylate	Yes
ozone depleting substances according to the Montreal Protocol	Yes
perfluoro-octanoic acid (PFOA), perfluoro-octane sulfonate (PFOS), perfluoro-alkyl phosphate esters (PAPs), perfluorinated carboxylic acids (PFCAs)	Yes
photo-initiators, including benzophenone, benzophenone derivatives, isopropyl thioxanthone (ITX), etc	Yes
phthalate plasticizers	Yes
phthalates used as technical support agent in polymer catalysis	Yes
polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)	Yes
polychlorinated biphenyls (PCB)	Yes
polycyclic aromatic hydrocarbons (PAH)	Yes
post-consumer recycled waste	Yes
PVC or PVDC	Yes
titanium acetyl acetonate (TAA) or acetyl acetone	Yes
triclosan	Yes
UV-curing components	Yes

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.

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. At such time we will inform our customers accordingly.



Thomas Catil
Lab Manager

Amcor Flexibles Sélestat SAS

2 rue Frédéric Meyer
BP 60128 - 67603 Sélestat Cedex
France
Tel: +33 (0)3 88 58 35 00