

<b>DECLARATION OF COMPLIANCE</b>
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Product name: Aluthene IV E110 /21 -E110/54 23PET  
 12IVE110/21- E110/54  
 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.**

<b>Aufbau / Composition</b>	<b>Dicke / Thickness [µm]</b>	<b>Grammatur / Unit mass [g/m<sup>2</sup>]</b>	<b>Dichte / Density [g/cm<sup>3</sup>]</b>
Extrusion coating		50	0.922
primer			1.021
Film PET	23	32.2	1.4
adhesive			1.047
Aluminium foil	12		2.71
Extrusion coating		50	0.922

The exact nature of the components used is Amcor Flexibles Sélestat proprietary information.

### **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 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.**

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 9.5 Edition CFR 177.1520 (2019)
primer		Regulation CONEG CFR 175.105 (2013) Regulation (EC) No 1935/2004 Regulation (EU) No 10/2011 amended up to (EU) No 2017/752 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
Film PET		CFR 177.1630 (2012) Regulation (EC) No 1935/2004 Regulation (EC) No 1895/2005 Regulation (EC) No 2023/2006 Regulation (EU) No 10/2011 Regulation (EU) No 10/2011 amended up to (EU) No 2017/752 Regulation (EC) No 1907/2006 amended up to (EU) No 412/2012
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 Regulation CONEG DIRECTIVE 2011/65/EU DIRECTIVE 2015/863 Regulation (EU) No 10/2011 amended up to (EU) No 2019/37 CFR 175.105 (2018)
Aluminium foil		Regulation (EC) No 1935/2004 Regulation (EC) No 2023/2006 CFR 178.3910 (2006) Directive 94/62/EC Standard EN 602 Regulation CONEG
Extrusion coating		Regulation (EU) No 10/2011 Regulation (EC) No 1935/2004 Pharmacopeia European Pharmacopoeia 9.5 Edition CFR 177.1520 (2019)

(\*) 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 and 2019/37. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.



Inside Layer	Component	Legal Provisions (recommendations, codes, decrees) for plastics, aluminium, paper / board, coatings and other components
Inside 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 Pharmacopoeia European Pharmacopoeia 9.5 Edition CFR 177.1520 (2019)

### 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/dm<sup>2</sup> as laid down in Regulation (EU) No 10/2011, does not apply to this product.

According to Directive 85/572, for dry products no tests of overall migration are required.

Note that also the compliance with specific restrictions on substances needs to be taken into account.

### 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.**

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.

FCM no	Name EU	n° CAS	Restriction	validation by
	1,6-HEXAMETHYLENE DIISOCYANATE HOMOPOLYMER	0028182-81-2	QMA 41 mg/dm <sup>2</sup> FCN 1692	finished product complies when the curing is complete
315	2,6-DI-tert-BUTYL-p-CRESOL (BHT)	0000128-37-0	QMA 0.06 mg/dm <sup>2</sup> Directive 2007/42/EC SML 3 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 CFR 175.105 (2019) CFR 175.125 (2019) CFR 175.300 (2019) CFR 175.380 (2019) CFR 176.210 (2019) CFR 177.1010 (2019) CFR 177.1350 (2019) CFR 177.2260 (2019) CFR 177.2600 (2019) CFR 178.2010 (2019) CFR 178.3570 (2019) CFR 181.24 (2019)	compliance is confirmed by our supplier

FCM no	Name EU	n° CAS	Restriction	validation by
377	3-AMINOPROPYLTRIETH OXSILANE	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 2019/1338 FCN 774 CFR 175.105 (2019) CFR 177.2355 (2019)	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 2019/1338 Decree Proposition 65 (2019)	compliance is confirmed by our supplier
115	CALCIUM ACETATE	0000062-54-4	QMA 2 mg/dm <sup>2</sup> QM 10000 mg/kg Directive 2007/42/EC SML 60 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 CFR 175.300 (2019) CFR 181.29 (2019)	compliance is confirmed by our supplier
106	Calcium stearate	0001592-23-0	QMA 2 mg/dm <sup>2</sup> QM 10000 mg/kg Directive 2007/42/EC SML 60 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 CFR 175.300 (2019) CFR 177.2410 (2019) CFR 177.2600 (2019) CFR 178.1010 (2019) CFR 178.2010 (2019) CFR 181.29 (2019)	compliance is confirmed by our supplier
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 2019/1338	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 2019/1338 FCN 735 CFR 177.1680 (2019) QM 100 mg/kg CFR 177.2450 (2019)	finished product complies when the curing is complete
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 2019/1338 FCN 85 FCN 360 FCN 376 FCN 547 FCN 635 FCN 1832 CFR 175.105 (2019) CFR 175.300 (2019) CFR 175.320 (2019) CFR 176.180 (2019) CFR 176.210 (2019) CFR 177.1390 (2019) CFR 177.2420 (2019) CFR 177.2800 (2019)	compliance is confirmed by our supplier

FCM no	Name EU	n° CAS	Restriction	validation by
227	Ethyleneglycol	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 2019/1338 FCN 8 FCN 9 FCN 13 FCN 14 FCN 72 FCN 85 FCN 179 FCN 348 FCN 355 FCN 360 FCN 376 FCN 477 FCN 547 FCN 616 FCN 617 FCN 635 FCN 689 FCN 844 FCN 937 FCN 1135 FCN 1234 Decree Proposition 65 (2019) CFR 175.105 (2019) CFR 175.300 (2019) CFR 175.320 (2019) CFR 175.390 (2019) CFR 176.170 (2019) CFR 176.180 (2019) CFR 176.210 (2019) CFR 176.300 (2019) CFR 177.1315 (2019) CFR 177.1345 (2019) CFR 177.1390 (2019) CFR 177.1500 (2019) CFR 177.1630 (2019) CFR 177.1637 (2019) CFR 177.1680 (2019) CFR 177.2420 (2019)	compliance is confirmed by our supplier
9; 10; 53	GLYCEROL MONOSTEARATE	0031566-31-1	Resolution Policy Silicones 2004 V.1 SML 60 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 CFR 175.210 (2019) CFR 175.300 (2019) CFR 176.170 (2019) CFR 176.200 (2019)	compliance is confirmed by our supplier
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 2019/1338 FCN 558 FCN 766 FCN 815 FCN 916 FCN 940 FCN 907 CFR 177.1680 (2019)	finished product complies when the curing is complete

FCM no	Name EU	n° CAS	Restriction	validation by
150	METHACRYLIC ACID	0000079-41-4	SML 6 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 FCN 3 FCN 69 FCN 106 FCN 244 FCN 332 FCN 646 FCN 684 FCN 778 FCN 845 FCN 862 FCN 884 FCN 885 FCN 933 FCN 1130 FCN 1145 FCN 1174 FCN 1177 FCN 1186 FCN 1188 FCN 1387 CFR 175.105 (2019) CFR 175.300 (2019) CFR 175.320 (2019) CFR 175.360 (2019) CFR 176.170 (2019) CFR 176.180 (2019) CFR 177.1010 (2019) CFR 177.1200 (2019) CFR 177.1330 (2019) CFR 177.1630 (2019) CFR 177.2420 (2019) CFR 177.2600 (2019) CFR 178.3790 (2019)	compliance is confirmed by our supplier
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 2019/1338 QM 2500 mg/kg FCN 124 QM 60 mg/kg FCN 181 QM 2500 mg/kg FCN 386 QM 2500 mg/kg FCN 768 QM 2500 mg/kg FCN 830 QM 600 mg/kg FCN 1206 QM 600 mg/kg FCN 1557 QM 667 mg/kg FCN 1605 QM 700 mg/kg FCN 1935 CFR 175.105 (2019) QM 100 mg/kg CFR 177.1010 (2019) QM 250 mg/kg CFR 178.2010 (2019)	compliance is confirmed by our supplier
509	PHOSPHORIC ACID	0007664-38-2	Resolution Policy Silicones 2004 V.1 SML 60 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 FCM 1857 CFR 175.300 (2019) CFR 177.2260 (2019) CFR 178.1010 (2019) QM 60000 mg/kg CFR 178.3520 (2019)	compliance is confirmed by our supplier

FCM no	Name EU	n° CAS	Restriction	validation by
399	POTASSIUM HYDROXIDE	0001310-58-3	Resolution Policy Silicones 2004 V.1 SML 60 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 CFR 175.210 (2019) CFR 176.210 (2019) CFR 177.1600 (2019) CFR 177.2800 (2019)	compliance is confirmed by our supplier
504	SILICON DIOXIDE	0007631-86-9	QMA 2 mg/dm <sup>2</sup> QM 10000 mg/kg Directive 2007/42/EC Resolution Policy Silicones 2004 V.1 Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 FCN 401 FCN 155 FCN 157 FCN 329 FCN 387 FCN 549 FCN 629 FCN 878 FCN 904 FCN 1073 FCN 1159 FCN 1235 CFR 175.105 (2019) CFR 175.350 (2019) CFR 176.170 (2019) CFR 176.200 (2019) CFR 176.210 (2019) CFR 177.1200 (2019) CFR 177.2250 (2019) CFR 177.2420 (2019) CFR 177.2600 (2019) CFR 178.3297 (2019) CFR 182.90 (2019)	compliance is confirmed by our supplier
116	SODIUM BENZOATE	0000532-32-1	QMA 2 mg/dm <sup>2</sup> QM 10000 mg/kg Directive 2007/42/EC Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 CFR 181.23 (2019)	compliance is confirmed by our supplier

FCM no	Name EU	n° CAS	Restriction	validation by
785	TEREPHTHALIC ACID	0000100-21-0	SML 7.5 mg/kg Regulation (EU) No 10/2011 amended up to (EU) No 2019/1338 FCN 8 FCN 9 FCN 13 FCN 14 FCN 85 FCN 103 FCN 179 FCN 360 FCN 376 FCN 380 FCN 417 FCN 423 FCN 473 FCN 547 FCN 635 FCN 727 FCN 742 FCN 745 FCN 844 FCN 852 FCN 874 FCN 875 FCN 907 FCN 916 FCN 937 FCN 1135 FCN 1170 FCN 1234 CFR 175.300 (2019) CFR 177.1345 (2019) CFR 177.1390 (2019) CFR 177.1500 (2019) CFR 177.1630 (2019) CFR 177.2420 (2019)	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/dm<sup>2</sup> units after division by the conventional conversion factor of 6 dm<sup>2</sup>/kg. This applies also to the finished food package if it contains less than 500 ml or more than 10 l.

#### **table 4b – substances in plastics authorised without SML in Regulation (EU) No 10/2011.**

Some or all of the authorised substances listed in table 4b may be present in the finished material.

This information is considered strictly confidential and may only be used for purposes of regulatory compliance assessments.

No.	PM ref.	Substance name	CAS no.
115	10090; 30000	CALCIUM ACETATE	0000062-54-4
106	24550; 89040	Calcium stearate	0001592-23-0



No.	PM ref.	Substance name	CAS no.
9; 10; 53	18115; 57520; 30610; 30612; 56585	GLYCEROL MONOSTEARATE	0031566-31-1
509	23170; 72640	PHOSPHORIC ACID	0007664-38-2
399	81600	POTASSIUM HYDROXIDE	0001310-58-3

This information is to the best of our knowledge and based on information received from our raw material suppliers, which may be incomplete. As there is no legal requirement to provide this information in the context of food contact compliance, incomplete or inaccurate information given in Table 4b cannot be the cause of any claim or rejection or other liability inferred upon us.

Substances without restrictions, which are also authorized as direct food additives, are only reported in Table dual additive below.

The substances listed in table 4c below are NIAS (non-intentionally added substances) that are known or expected to be present in the material. Further details about these substances can be discussed separately on a case by case basis. The table includes the summary of our provisional risk assessment for these substances; this also can be discussed separately.

**table 4c – NIAS known or expected to be present in the material.**

CAS no.	Substance name	Evaluation
None		

## **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 by Regulation (EC) No 1333/2008. In absence of a Community reference list of these substances, or a marking in the Regulation, the following information received from our suppliers, can only be considered preliminary:

**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)
E 263	CALCIUM ACETATE
E 470 a	Calcium stearate
E 471	GLYCEROL MONOSTEARATE
E 338	PHOSPHORIC ACID
E 525	POTASSIUM HYDROXIDE
E 551	SILICON DIOXIDE
E 211	SODIUM BENZOATE

## **List of Components (LoC)**

To the best of our current knowledge the above information on restricted and non-restricted substances listed for plastics, is complete. Therefore a separate LoC is not required.

## **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 the assessment of NIAS is part of our supporting documentation and is available to

the authorities on their request.

## **Environmental Compliance**

Our product is manufactured in compliance with Directive 94/62/EC on Packaging and Packaging Waste, as amended by Directive 2004/12/EC. More specifically, the combined total amount of Lead, Cadmium, Mercury and hexavalent Chrome in above-mentioned material does not exceed 100 ppm and no substances dangerous to the environment are purposely used in manufacturing our product.

## **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.

## **Absence of chemical substances**

This product has been manufactured from raw materials which, according to the information available to us, do not intentionally contain:

<b>Substance</b>	<b>Not constitutional component</b>
acrylamide	Yes
asbestos	Yes
allergens listed in Annex II of Regulation (EU) No 1169/2011 as amended	Yes
azodicarbonamide and semicarbazide	Yes
brominated flame retardants	Yes
biocides and fungicides incl. dimethyl fumarate, paraben	Yes
Bisphenol A, Bisphenol S	Yes
Bisphenol A Diglycidyl Ether (BADGE), Bisphenol F Diglycidyl Ether (BFDGE) or Novolac Glycidyl Ethers (NOGE)	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

Substance	Not constitutional component
photo-initiators, including benzophenone, benzophenone derivatives, isopropyl thioxanthone (ITX), etc	Yes
phthalate plasticizers	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
phthalates used as technical support agent in polymer catalysis	Yes

The presence of these substances in our finished product is not expected, but has not been confirmed by testing. Trace impurities cannot be excluded.

## **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.

Marie-Helene Fremont-Obser  
Responsible Laboratoire

### **Amcor Flexibles Sélestat SAS**

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