Main information

Description

This Technical and Compliance File relates to Pouch OPA/ALU/PE 12/9/50 and OPA/ALU/PE PEEL 12/9/50 which is called below as “product”.

This product can also be called:

- Pouch OPA/ALU/PE PEEL

Quality Management System

Südpack Medica SAS complies with the requirements of ISO 9001:2015, ISO 13485:2016 and ISO 15378:2017.

Responsibilities

The information contained herein is based on the confirmations of the suppliers, chemical, physical and biological studies and our present state of knowledge. Users should consider these data only as a supplement to other information. A legally obligatory warranty of certain information as well as suitability for the specific application cannot be derived from this declaration. The determination of the specific suitability of this product for individual applications is the sole responsibility of the purchaser.

As set forth in the specifications, Südpack Medica SAS manufactures and delivers the products with one (1) or three (3) seal(s). Südpack Medica SAS herewith explicitly points out, that the 2nd or 4th seal of the Product is done by the customer itself on its own responsibility.

Compatibility with sterilization

This product is suitable with the following sterilization methods:

- E-Beam
- Gamma Irradiation

Product composition

This product is composed:

- One side of "OPA/ALU/PE 12/9/50" (see Technical and Compliance File "OPA.ALU.PE 12.9.50")
- One side of "OPA/ALU/PE PEEL 12/9/50" (see Technical and Compliance File "OPA.ALU.PE PEEL 12.9.50")

REACH

REACH is the Regulation, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1St June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (UE). Manufacturers and importers of chemicals and also all users are required to manage the risks that chemicals may pose to the health and the environment.

Südpack Medica SAS has the status if a Downstream User, has determined that the supplied articles do not requires any registrations/pre-registration with the ECHA, since there is no "international release" of chemical substances.

Based on information available from our raw material suppliers and at our current levels of knowledge, none substances or candidate substances of very high concern as published on the draft list issued by ECHA are present at 0,1% weight by weight.

Last update: ECHA - Candidate List of SVHC 23.01.2024

https://echa.europa.eu/candidate-list-table

If in future a new candidate material in the products we deliver to you be included at concentrations above 0.1% (w/w), we will voluntarily provide information under Article 33 of our legal and comply with REACH delivery.

Safety Data Sheet

As this product complies with REACH Regulation EC 1907/2006 (see above), it is considered non-hazardous and does not require a safety data sheet.

Storage recommendation

Recommended storage conditions are:

- at a temperature between 10 and 30 °C
- at a humidity between 40 and 60 % r.H.
- protected from sunlight
- not in proximity of a source of heat
- in original packaging
- It is advised to store the reels for at least 24 hours prior to use in the production hall, in order to bring the packaging film at manufacturing temperature.

Microbiology tests

We do not commit for a certain level of Bioburden. However, we perform microbiological tests every week (for ISO 7 clean room) or every month (for ISO 8 clean room) in our environment, on our machines and randomly on several types of products to follow our level of cleanliness. Our monitoring plan has been developed in accordance with the NF EN 17141 (2020) “Cleanrooms and related controlled environments - Biocontamination control” and our products are manufactured in ISO 7 or 8 cleanroom.

Standards

Compliance with 11607-1

This product complies with the standard NF EN ISO 11607-1 (2020).

Compliance with 11607-2

This product complies with the standard NF EN ISO 11607-2 (2020) except for chapters 6 and 7.

Compliance with 868-5

This product complies with the chapter 4.5.1 of the standard EN 868-5 (2018).

Regulatory data

Bisphenol A and Phthalates

Hereby we confirm that neither our supplier, nor Südpack Medica SAS, intentionally use this substance as part of recipe or in the manufacturing process of this material.

Epoxy derivates

Hereby we confirm that neither our supplier, nor Südpack Medica SAS, intentionally use this substance as part of recipe or in the manufacturing process of this material.

Animal substances - 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.

Our supplier therefore is certain that no danger for human health can result from the use of the above-mentioned additives and, by extension, this product.

Nanomaterials – Recommendation 2011/696 EU

Hereby we confirm that, to the best of our knowledge and based on our supplier's declaration, this product complies with the following regulation:

- Nanomaterials defined according to recommendation 2011/696 EU are no constitutional element of our film except for silica which is non-migratory.

Regulation of food packaging

Hereby we confirm that, to the best of our knowledge and based on our supplier's declaration, this products complies with the following regulations :

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

Food allergen

Hereby we confirm that our supplier does not intentionally use allergens as part of recipe or in the manufacturing process of this material.

Hereby we confirm that, to the best of our knowledge and based on our supplier's declaration, this product complies with the following regulations:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004

Heavy metals

The composition of the product when leaving the factory complies with the specific requirements of heavy metal concentration limits of the CONEG and the directive 94/62/EC: lead, mercury, cadmium and hexavalent chromium are not intentionally added to the product, and the incidental sum of the concentrations does not exceed 100 ppm by weight.

Latex - Naturel rubber

Hereby we confirm that neither our supplier, nor Südpack Medica SAS, intentionally use this substance as part of recipe or in the manufacturing process of this material.

Mineral oil - MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons)

Hereby we confirm that neither our supplier, nor Südpack Medica SAS, intentionally use this substance as part of recipe or in the manufacturing process of this material.

PFAS

Hereby we confirm that our supplier does not intentionally use PFOS (Perfluorooctanesulfonic acid – CAS Nr.: 1763-23-1) and PFOA (Perfluorooctanoic acid – CAS Nr.: 335-67-1) as part of the recipe or in the manufacturing process of the product.
PFAS are not intentionally added by Südpack medica SAS during our production processing our recipes or manufacturing processes. However, certain low-level additives are used in the plastics converting industry widespread, containing two PFAS (Hexafluoropropene – CAS Nr.: 116-15-4) and (1,1-difluoroethylene – Nr.: CAS 75-38-7:) in very low concentrations.
The use of these additives is generally considered unavoidable in many different types of plastics. The purpose of them is that the mentioned PFAS are very volatile and adhere to the extruder walls to ensure better flow.
However, it has to be pointed out that:

- these substances are approved for food-contact use according to EU 10/2011
- the concentration of the two PFAS in these additives is so low that the specific limits mentioned in the EU 10/2011 are far below even in case of 100% migration. Furthermore, it can be expected that they will evaporate during the extrusion process due to their volatility

PVC - PolyVinyl Chloride

Hereby we confirm that neither our supplier, nor Südpack Medica SAS, intentionally use this substance as part of recipe or in the manufacturing process of this material.

Validity of this Technical and Compliance File

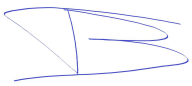
This declaration is given in good faith and to the best of our current knowledge, according to our supplier's declaration. It doesn't release from the responsibility to check the suitability of packaging material for the proposed application.

This declaration is valid for 18 months after the date as stated on the top of this page only and expires thereafter, without any further notice being required. Furthermore, any information of this declaration may be subject to change at any time.

Pouch OPA/ALU/PE 12/9/50 and OPA/ALU/PE PEEL 12/9/50				
Parameter	**Method**	**Value**	**Value**	**Unit**
		OPA/ALU/PE 12/9/50	**OPA/ALU/PE PEEL 12/9/50**	
Thickness (total)	ASTM D374	79	79	µm
Thickness (per layer) Oriented PolyAmide	ASTM D374	12	12	µm
Thickness (per layer) Adhesive	ASTM D374	4	4	µm
Thickness (per layer) Aluminium	ASTM D374	9	9	µm
Thickness (per layer) Adhesive	ASTM D374	4	4	µm
Thickness (per layer) PolyEthylene	ASTM D374	50	50	µm
Weight (total)	ASTM D4321	93,4	93,4	g/m²
Weight (per layer) Oriented PolyAmide	ASTM D4321	13,8	13,8	g/m²
Weight (per layer) Adhesive	ASTM D4321	4,5	4,5	g/m²
Weight (per layer) Aluminium	ASTM D4321	24,3	24,3	g/m²
Weight (per layer) Adhesive	ASTM D4321	4,5	4,5	g/m²
Weight (per layer) PolyEthylene	ASTM D4321	46,3	46,3	g/m²
Breaking elongation (CD)	ASTM D882	81	89	%
Breaking elongation (MD)	ASTM D882	91	94	%
Tensile strength (CD)	ASTM D882	49*	52*	N/mm²
Tensile strength (MD)	ASTM D882	55*	55*	N/mm²
Oxygen Transmission Rate (OTR)	ASTM D3985 23°C & 50%RH	< 0,1*	< 0,1*	cm³/m².d. atm
Water Transmission Rate (WTR)	ASTM E96 38°C & 90%RH	< 0,1*	< 0,1*	g/m².d
Recommanded sealing Parameters (temperature)	Supplier method	120 - 200	120 - 200	°C
Recommanded sealing Parameters (time)	Supplier method	0,5 – 2,0	0,5 – 2,0	s
Recommanded sealing Parameters (pressure)	Supplier method	2,0 – 5,0	2,0 – 5,0	bar

* Elongation destroys the barrier properties of the packaging material (foil is damaged beyond 4% elongation)

Revision history		
Version	**Date**	**Subject of the review**
1	29/01/2024	Creation of the document. This document cancels and replaces the following documents: • FT57V11 • Statement “ISO 11607-1 OPA12ALU9PE50 peel” • Statement “DOC_OPAALUPEPEEL” • Statement “REACH”
2	22/05/2024	Update REACH list to 23/01/2024

Signature
 Thomas BAZIN, Responsable Qualité Système 2024.05.22 11:06:26 +02'00'