

1. Identity of the declaring operator

Name: BELLO Céline

Function: Quality Manager

Name and address of the Company: ALUPLAST / Z.A.C de la prévôté - 9 Route de BU - 78550 HOUDAN France

2. Identity of the operator who manufactures or imports the material and/or article that is the subject of the declaration : confidential

3. Identity of the material and/or object being declared :

DESIGNATION	REFERENCE	
Pre-cut cling film	FILM PRE 30X30 FILM PRE 40X40 FILM PRE 46X46	

Indicate the components of the material(s) that make up the structure of the object:

Material Family	Aluminium	Wood	Paper/carton	Plastic
				X

Characteristic components, from the inside out : **PVC stretch film factor 2**

Issue date : 10/10/2023

4. Confirmation of the conformity of the material and/or object that is the subject of the declaration

- Regulation (EC) No. 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with foodstuffs;
- Regulation (EU) No 2023/2006 of 22 December 2006, as amended, on good manufacturing practice for materials and articles intended to come into contact with foodstuffs;
- Regulation (EU) No 10/2011 and its amendments
- The manufacturing facility has the following approvals:
 - Quality: ISO 9001 issued by AFNOR (French Association for Standardization)
 - Hygiene: BRC/IoP Hygiene Standards according to the principles of the HACCP (Hazard Analysis and Critical Control Point) concept and issued by the LNE (National Testing Laboratory).

This declaration of conformity has been drawn up on the basis of the following :

- ☐ Declarations from suppliers of raw materials (component of the material/object)
- ☒ Manufacturing Plant Declarations
- ☒ Global migration scans (if applicable)

5. Global Migration Analytics:

Simulants	Maximum contact time	Temperature
(A) Ethanol 10%	10 days	40 °C
(b) Acetic Acid 3%	10 days	40 °C
(D2) Vegetable oil	10 days	40 °C

Migration tests are carried out each year through external laboratories with recognized accreditations: Laboratoire National d'Essais (LNE), Trappes, France / CSI Spa, Bollate, Italy / RESCOLL, Pessac, France

- Testing of Restricted Substances
- Unintentionally Added Substances (NIAS)
- Risk assessment carried out in accordance with Article 19 of Regulation (EU) No 10/2011

6. Information on Restricted Substances

Monomer(s)/Additive(s)	Réf.PM	Specific Migration Limit (ppm)
Acetic acid, vinyl ester	10120	12
Adipic acid, bis(2-ethylhexyl) ester	31920	18
ESBO, epoxidised soybean oil	88640	60
Formaldehyde-1-naphthol, copolymer	54930	0,05
Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C12-C18 or n-octanol and/or n-decanol	76866	30
Terephthalic acid, bis(2-ethylhexyl) ester	92200	60
VCM, vinyl chloride monomer	26050	0,01
Zn	/	5

Based on the food safety declarations issued by its suppliers, the manufacturing plant assures us that the migration of these substances from the films we deliver to you is below the maximum limit imposed (the verification of this conformity is done either by calculation of the worst case or by using a specific migration test).

7. Information on dual-use additives

☐ Not applicable

To the best of our knowledge and based on our supplier's statements, the film contains the following dual-functional additives:

Dual-Functionality Additive(s)	Ref. PM	E Number	Conc.Maxi (ppm)
Acetylated mono- and diglycerides of fatty acids	30401	E472a	80000
Sodium hydrogen carbonate	42500	E500	100

8. Organoleptic taste test in accordance with Regulation (EC) 1935/2004

Next UNI 10192/2000

The taste rating test is an assessment of taste, measured using a 5-point scale. Each judge is invited to taste water samples from contact with the specimens. They are then asked to rate each sample of water they taste, according to the following scale:

- 0: No noticeable difference in taste
- 1: Barely noticeable difference, very difficult to define
- 2: Slight difference but identifiable taste
- 3: Strong Taste Difference
- 4: Very strong difference in taste

The final result is expressed as the average value of the scores awarded by each judge, coupled with the standard deviation.

Test Conditions:

- Shelf life: 18 hours
- Storage temperature: 55°C ± 1°C

- Sample quantity: 1.5 dm²
- Food simulator: Levissima natural water
- Panel Members: 6

The sample is recognized as having a potential organoleptic impact on the product if the mean score plus one standard deviation is greater than or equal to 3.

Sample	Average value	Standard Deviation
PVC cling film	2.3	0.5

Uncertainties are estimated as a broad uncertainty obtained by multiplying the standard uncertainty by the coverage factor k corresponding to a confidence level of about 95%. Normally, this factor = 2.

9. Olfactory organoleptic test in accordance with Regulation (EC) 1935/2004

Next UNI 10192/2000

The olfactory scoring test is an assessment of smell, measured using a 5-point scale. Each judge is asked to smell a series of dark coded vials containing the samples. They are then asked to give each vial a score:

- 0: No noticeable smell
- 1: Little noticeable smell, very difficult to define;
- 2: Faint but identifiable odor;
- 3: Strong smell;
- 4: Very strong smell

The final result is expressed as the average value of the scores awarded by each judge, coupled with the standard deviation.

Test Conditions:

- Shelf life: 18 hours
- Storage temperature: 55°C ± 1°C
- Sample quantity: 1.5 dm²
- Jar volume: 500 ml:
- Panel Members: 6

The sample is recognized as having a potential organoleptic impact on the product if the mean score plus one standard deviation is greater than or equal to 3.

Sample	Average value	Standard Deviation
PVC cling film	2	0.6

Uncertainties are estimated as a broad uncertainty obtained by multiplying the standard uncertainty by the coverage factor k corresponding to a confidence level of about 95%. Normally, this factor = 2.

10. Information about the end use of the material or object

Material or object intended for infant feeding

☐ Yes

☒ No

Type of food intended to be brought into contact:

	YES	NO
In contact with all types of food		X
or only:		
In contact with dry goods	X	
In contact with wet/aqueous products	X	
In contact with fatty foods: factor 2	X	
	<i>Butter and margarine yes but not 100% fatty and oil foods, foods preserved or marinated in an oily environment</i>	
In contact with acidic foodstuffs	X	
In contact with alcoholic products below 5%v/v alcohol	X	
In contact with frozen foodstuffs	X	
	<i>Freezer (recommended test to validate the mechanical performance of the film)</i>	
Other contact (to be specified)		

The films mentioned are products to be in contact with food.



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They are suitable for contact with all foods for which simulants A, B and D2 are intended taking factor 2 into account.

The film is therefore suitable, for example, for food packaging such as:

- Fruits and vegetables and frozen products.
- Meat
- Pisces
- Sandwich,
- Cheese
- Margarine and butter, with the exception of fatty products, or fatty products on the surface or preserved or marinated in oily environments, including animal and vegetable fats and oils, nuts in paste or cream form, sauces in a fatty character and spices and aromatics in oily environments.
- The products are single-use only and have not been tested for repeated use.

The following processing and storage times and temperatures in contact with the food:

- Any storage less than 30 days at room temperature
- Any long-term storage in a refrigerated and frozen state
- Freezer (recommended test to validate the mechanical performance of the film)
- Heating at a maximum of 70°C for a maximum of 2 hours or heating at a maximum of 100°C for a maximum of 15 minutes (be careful not to use in the traditional oven, infrared oven and multifunction oven)
- In the microwave: can be used for defrosting and reheating without contact with food

Not suitable for the following uses:

- Traditional, infrared and multifunction oven
- Packaging of 100% fatty or oily foods, foods preserved or marinated in an oily environment and nuts in paste or cream form

11. Maximum ratio of surface area in contact with the foodstuff / Volume used to establish the conformity of the material or object : 6 dm²/kg

12. According to our manufacturing facility, the following substances are not intentionally introduced during the manufacture of our films :

- Phthalates
- BADGE, NODGE & BFDGE
- BPA (Bisphénol A)
- Nanoparticles
- Acrylamide
- Alkylphenols and Alkylphenol ethoxylates belonging to the group of potential oestrogen mimics -

Specifically - nonylphenol, octylphenol, butylphenol, dodecylphenol

- Allergens as described in Annex II, Reg (EU) N° 1169/2011
- Antibiotics
- Antimony and Antimony compounds
- Aromatic amines
- Arsenic and Arsenic compounds
- Asbestos
- Azo compounds
- Bamboo and its derivatives
- Benzene
- Beryllium and Beryllium compounds
- Bisphenol compounds: BPA, BPB, BPC, BPE, BPF, BPS, BPZ and BPA bis(phthalic anhydride)

CAS 3813-06-9

- Butylated Hydroxyanisole (BHA)
- Cadmium and Cadmium compounds
- Chlorofluorocarbons (CFCs) or Hydrochlorofluorocarbons (HCFCs)
- Chlorinated paraffins
- Cytotoxic products
- Dimethylfumarate (DMF)
- 1,4 - Dioxane

¹ This declaration, based on the ANIA 2019 model, concerns materials and articles intended to come into contact with foodstuffs as defined in the scope of Regulation 1935/2004/EC and Sanction Decree No. 2007-766 of 10 May 2007 as amended

- Dioxins or furans
- Epoxy derivatives listed in EU Regulation (EC) No 1895/2005
 - Bisphenol A diglycidyl ether (BADGE) (CAS # 1675-54-3)
 - Bisphenol F diglycidyl ether (BFDGE) (CAS # 39817-09-9)
 - Novolac Glycidyl Ethers (NOGE)
- Formaldehyde
- Fungicides, pesticides, condoms, or fumigants
- Glymo, 3-(2,3-epoxypropoxy)propyltrimethoxysilane
- GMO (genetically modified organisms)
- Halogenated (Brominated or chlorinated) or phosphorous based flame retardants
- Hormone products
- Irradiated materials
- Isocyanates
- Latex
- Lilial (butylphenyl methylpropional)
- Melamine
- Mercury and Mercury compounds
- Methyl salicylate
- Mineral oils (MOSH/MOAH).
- Nano materials
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nickel and nickel compounds
- Nitrofurazone (CAS 59-87-0)
- Nitroso compounds
- Organotin compounds
- Oxo-degradable material
- Parabens
- Perchlorates
- Pesticides as defined in Regulation (EC) N° 1107/2009
- Phthalates / Phthalate esters
 - DEHP (Bis(2-ethylhexyl) phthalate)
 - DBP (Dibutylphthalate)
 - BBP (Benzylbutylphthalate)
 - DiBP (Diisobutylphthalat)
 - DHNUP (1,2-Benzenedicarboxylic acid di(C7-C11) alkyl ester)
 - DIHP (Diisoheptyl phthalate)
 - DMEP (Bis(2-methoxyethyl) phthalate)
 - DIPP (Diisopentyl phthalate)
 - DPP (Dipentyl phthalate)
 - 1,2-benzenedicarboxylic acid dipentyl ester, branched and linear
 - n-pentyl isopentyl phthalate
 - Dihexyl phthalate
 - 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear
- Photoinitiators, including
 - Benzophenone
 - Hydroxybenzophenone
 - 4-methylbenzophenone
 - Isopropylthioxanthone (ITX)
 - 2-hydroxy-2-methylpropiophenone
- Polycyclic Aromatic Hydrocarbons (PAHs)
 - Benzo[a]pyrene (CAS 050-32-08)
 - Benzo[e]pyrene (CAS 192-97-2)
 - Benzo[a]anthracene (CAS 056-55-3)
 - Benzo[b]fluoranthene (CAS 205-99-2)
 - Benzo[j]fluoranthene (CAS 205-82-3)
 - Benzo[k]fluoranthene (CAS 207-08-9)
 - Chrysene (CAS 218-01-9)
 - Dibenzo[a,h]anthracene (CAS 053-70-3)
 - Benzo [g,h,i]perylene (CAS 191-24-2)

- Indeno[1,2,3-cd] pyrene (CAS 193-39-5)
- Acenaphthylene (CAS 208-96-8)
- Ancenaphthene (CAS 083-32-9)
- Fluorene (CAS 086-73-7)
- Phenanthrene (CAS 085-01-8)
- Pyrenees (CAS 129-00-0)
- Anthracene (CAS 120-12-7)
- Fluoranthene (CAS 206-44-0)
- Naphthalene (CAS 091-20-3)
- Polybrominated Diphenyl Ethers (PBDEs)
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- Polychlorinated and Polybrominated Naphthalenes
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Polyvinylidene Chloride (PVDC)
- Post-consumer recycled material
- Primary Aromatic Amines (PAA)
- Radioactive Substances
- Semicarbazide (CAS 57-56-7)
- Substances of Very High Concern on the Candidate List of REACH (reg (EC) n°1907/2006) at concentration > 0.1 wt%
- Silver and silver compounds
- Styrene
- Sulfonamides
- Toluene
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether)
- Tris(nonylphenyl)phosphite (TNPP)
- Xylene

13. Storage Instructions:

- Store in a dry, clean and well-ventilated area without direct sunlight or heat.
- 15/20°C away from moisture. Film properties can be changed under extreme storage conditions.
- We recommend using our films within a maximum of 12 months after delivery.

14. Traceability of information:

As required by Regulation (EC) 1935/2004, Article 17, ALPINLAST's supplier has in place the necessary systems, records and procedures to ensure the traceability of the material and its items at all stages of manufacture in order to facilitate the control and recall of defective products.

15. Certificate of compliance with the provisions of Directives 94/62/EC and 2004/12/EC and Decree 2007/1467 (repealing Decree No. 98-638) relating to environmental requirements.

Part 1: Summary of Evaluation

Standard/Report	Assessment Requirement	Answer	Note
1.1 Prevention by source reduction	Ensure only a minimum adequate amount of material in the packaging system (norms NF EN 13428)	Yes	The dimensions meet the customer's request.
1.2 Heavy metals	Ensure levels below the maximum allowable for components (CR 13695-1)	Yes	The total concentration for the 4 heavy metals (lead, cadmium, mercury and chromium VI) is less than 100ppm
1.3 Other Harmful/Hazardous Substances	Ensure compliance with the standard EN 13428	Yes	
2. Reuse	Ensure reusability in all terms of the standard for the functional unit of the packaging (standard NF EN 13429)	No	The use of our packaging components requires them to be modified (cutting, welding, etc.) so no reuse is possible.

3.1 Recovery by material recycling	Ensure recyclability in all terms of the standard for the functional unit of packaging (EN 13430 standard)	No Applicable	Cleaning our products in contact with food would be too expensive.
3.2 Recovery in the form of energy	To ensure the achievement of a heat gain for the functional unit of the packaging (EN 1343 standard)	Yes	"Packaging made of more than 50% organic matter... must be considered as energy-recoverable." (EN 13431: 1999)
3.3 Recycling by composting	Ensure compostability in all terms of the standard for the functional unit of packaging (standard EN 13432)	No Applicable	Standard plastic materials are not suitable for composting.

Note: Compliance with the EU Directive requires affirmative answers to paragraphs 1.1, 1.2 and 1.3 and at least one of paragraphs 3.1, 3.2, 3.3. In addition, where re-use is claimed, an affirmative answer should also be recorded in paragraph 3.

In view of the evaluation results recorded in Part 1 above, this packaging is declared to comply with the requirements of EN 13427, it therefore complies with the provisions of Book V of the Environmental Code (Articles R 543-42 to R 543-49), consolidated version of 01/09/08 and Decree 2007-1467.

16. REACH Compliance:

Regarding the REACH regulation, which came into force on 1 June 2007, our manufacturing plant is a user of raw materials and consequently, the pre-registration and/or registration of chemical substances is deployed by its raw material suppliers.

As a manufacturer of articles (plastic films for food contact made from chemical raw materials), our manufacturer has a duty to ensure that applications like yours are registered with the European Chemical Agency in Finland (ECHA). These substances were pre-registered prior to 01/12/08.

If, however, you are using the films for non-food packaging application, please let us know as soon as possible.

Our manufacturer is a member of the French plastic and flexible packaging association ELIPSO and the EFMA (European Polyvinyl Film Manufacturers Association).

Regarding the very dangerous substances (classified SVHC in particular) present in the latest list in force, films are not concerned since our manufacturer does not use them or is very much below the limit (< 1000 ppm), the films being intended for food contact.

The declaration is based on the documentation of the raw material suppliers and/or the finished product manufacturer .

This declaration is valid only for the material or object as delivered (empty packaging), and as long as there is no regulatory change or change that could result in a change in the inertia of the material or article.

In any case, compliance is understood subject to compliance with the conditions of storage, handling and use taking into account the particular characteristics of the material or object, conditions as provided for by customs or professional codes.

In the event of a change in the characteristics of the packaged product, its composition or its intended use, as well as in the event of a change in the conditions of use of the material or object, the person to whom this declaration is addressed must ensure the compatibility of the container/content, for which he or she is then solely responsible.

However, the warranty cannot be extended to:

- Any subsequent changes in the composition of the product covered by this declaration, by the addition of substances of any kind;
- Processing that may lead to a denatured material;
- Incorrect use of materials;



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- Verification of the reciprocal compatibility of the material and the packaged foodstuffs, which is the sole responsibility of the packaging user packaging the packaged foodstuffs with regard to its industrial process and the composition of these foodstuffs, and in particular the non-modification of the organoleptic characteristics of the packaged foodstuffs.
- The use of the products covered by this declaration is subject to verification of their conformity with the standards in force and their technical conformity with respect to the use for which they are intended.

This declaration takes effect from the date indicated, for a maximum period of 3 years. It cancels any previous declarations.

This declaration remains valid as long as the material or object referenced has not been subject to a change that may affect its suitability for food contact.

Any change in the subject matter and/or regulations in force regarding this statement will result in its revision.

We are only liable for this statement to the extent that our suppliers' declarations are compliant.

This declaration is made pursuant to Article 16 of Regulation 1935/2004/EC, as well as Decree No. 2008/1469 of 30/12/2008 amending Decree No. 2007-766 implementing the Consumer Code with regard to materials and objects intended to come into contact with foodstuffs.

It is intended for the company: **E. Weber & Cie AG**

Date **1/8/2024**