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# DECLARATION OF CONFORMITY

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**Article:** transparant PP sheets

**Customer:** Bruyerre

**Customer art. ref.:** 24605020    **Bande Bavarois précoupe 39 x 250 mm EP 40µm**  
24605045    **Rectangle cello 100x130mm ep 40 µm**

**1. ISSUE DATE** 2023-12-13

## **2. APPLICABLE LEGISLATION AND PURITY CONFIRMATION**

### **European Commission Regulation definition:**

– 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, (hereinafter referred to as "Regulation (EC) No 1935/2004").  
– 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, amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").

### **3. A. Europe**

#### **i. Compliance with the requirements of the Framework Regulation**

- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General safety aspects: YES
- Article 11(5) of Regulation (EC) No 1935/2004; Community authorisation: YES
- Article 15 of Regulation (EC) No 1935/2004; Labelling: YES
- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

#### **ii. Compliance with the requirements of the Plastics Regulation**

- Regulation (EU) No 10/2011: YES

Plastics used to produce this Product are manufactured from only monomers, other starting substances and additives authorized under Regulation (EU) No 10/2011.

#### **iii. Other EU legislation**

Other EU legislation: NOT SPECIFIED

***With regards to 2023/1442: Plastics materials and articles complying with Regulation (EU) No, 10/2011 as applicable before the entry into force of this Regulation, which were first placed on the market before 1 February 2025 may remain on the market until the exhaustion of stocks.***

### **5 B. Member State legislation and non-European legislation**

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

National legislation in EU Member States		
Material group	Status	Legislation
GENERAL <b>Country:</b> Germany - Food and Feed law	Compliant	Legislation is made under powers of the Lebensmittel- und Futtermittelgesetzbuch [Food and Feed law], Bedarfsgegenständeverordnung v. 23.12.1997, including LFGB § 30, 31 and 33 as amended up to Verordnung vom 15 Februar 2016 (BGBl. I S. 198).
PLASTICS <b>Country:</b> Belgium - A.R. du 11/05/1992	Compliant	A.R. du 11/05/1992 concernant les matériaux et objets destinés à entrer en contact avec les denrées alimentaires. [M.B. du 24/07/1992] as amended by date
<b>Country:</b> Italy	Compliant	Ministerial Decree of 21 March 1973 as amended up to Decree No. 195 of 06 August 2015.
<b>Country:</b> Netherlands - Hoofdstuk I – Kunststoffen (26 april 2022)	Compliant	Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen), geamendeerd tot aan Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 26 april 2022, 3348384-1027396-VG. Chapter I - Plastics
Legislation for countries outside the EU		
Material group	Status	Legislation
GENERAL <b>Country</b> United Kingdom - UK Statutory Instruments 2019 No. 704	Compliant	The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (No. 704) <u>Specifications of use</u> n/a
PLASTICS <b>Country</b> Switzerland - 817.023.21	Compliant	Ordonnance du DFI 817.023.21 sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires (Ordonnance sur les matériaux et objets) du 16 décembre 2016 (Etat le 1er mai 2017). Section 5 Matériaux et objets en matière plastique. <u>Specifications of use</u> n/a
<b>Country</b> Switzerland - 817.023.21, Annex 2 (Edition 2,0)	Compliant	Ordonnance 817.023.21 du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires (Ordonnance sur les matériaux et objets) du 16 décembre 2016 (Etat le 1er décembre 2019) Annex 2 to the DFI ordinance on materials and articles intended to come into contact with foodstuffs <u>Specifications of use</u> n/a
<b>Country</b> Turkey	Compliant	Notification No.2019/44 - referring Regulation EU No.10/2011 <u>Specifications of use</u> n/a
<b>Country</b> United States - § 177.1520	Compliant	TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED) PART 177 INDIRECT FOOD ADDITIVES: POLYMERS B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces § 177.1520 - Olefin polymers. <u>Specifications of use</u> Food types : I-IX. Conditions of use C-H.

### 5. C Non-intentionally added substances

Non-intentionally added substances in plastics, according to Article 6(4a) of Regulation (EU) No 10/2011, and in non-plastic materials, are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004.

### 5. D Overall migration limit

Overall migration test was carried out on the film itself or on films with comparable composition. Overall migration is tested under the following conditions:

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**Simulants**

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- A - Ethanol 10% (v/v)
  - B - Acetic acid 3% (w/v)
  - D2 (assigned fatty food simulant) - Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011.
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**Test conditions**

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<b>Test Number</b>	<b>Test conditions</b>	<b>Intended food contact conditions</b>	<b>Covers also food contact conditions described for</b>
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.	Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.

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**5. E. Organoleptic properties**

We have performed some sensory tests on this film type following test method **DIN 10955:2004**. Sensory test results indicate either no noticeable change or barely noticeable change of odour and flavour.

## 6. LIMITS, RESTRICTIONS AND COMPOSITIONAL SPECIFICATIONS

### 6. A. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

Substance identification	Restriction(s)	Restrictions and specifications	Maximum concentration IN FILM	Compliance screening method (Migration results if method 4)
<b>FCM:</b> 779 * <b>EEC ref:</b> 39815 <b>CAS:</b> 0182121-12-6 <b>Substance name:</b> 9,9-bis(methoxymethyl)fluorene	<b>SML:</b> 0,05 mg/kg	<b>Notes:</b> Note number (2): There is a risk that the SML or OML could be exceeded in fatty food simulants. <b>Fat-reduction factor:</b> yes	2,565 ppm	Method= (1) <b>(Migration results:</b> -)
<b>FCM:</b> 185 <b>EEC ref:</b> 20440 <b>CAS:</b> 0000097-90-5 <b>Substance name:</b> methacrylic acid, diester with ethyleneglycol	<b>SML:</b> 0,05 mg/kg	<b>Fat-reduction factor:</b> no	6,000 ppm	Method= (1) <b>(Migration results:</b> -)

<p><b>FCM:</b> 760 *</p> <p><b>EEC ref:</b> 83595</p> <p><b>CAS:</b> 0119345-01-6</p> <p><b>Substance name:</b> reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl</p>	<p><b>SML:</b> 18 mg/kg</p>	<p><b>Other Specifications:</b></p> <p>Composition: 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)),4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)),3,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)),4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)),tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)),4,4'-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (&lt; 5 % w/w (*))(*Quantity of substance used/quantity of formulationOther specifications: Phosphor content of min. 5,4 % to max. 5,9 %,Acid value of max. 10 mg KOH per gram,Melt range of 85- 110 °C,</p> <p><b>Fat-reduction factor:</b> no</p>	<p>36,188 ppm</p>	<p>Method= (1) <b>(Migration results:</b> -)</p>
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<b>FCM:</b> 688 <b>EEC ref:</b> 92560 <b>CAS:</b> 0038613-77-3 <b>Substance name:</b> tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	<b>SML:</b> 18 mg/kg	<b>Fat-reduction factor:</b> yes	4,158 ppm	Method= (1) <b>(Migration results:</b> -)
<b>FCM:</b> - * <b>EEC ref:</b> - <b>CAS:</b> - <b>Substance name:</b> Group 7	<b>SML:</b> 1,2 mg/kg	<b>SML(T) Remark:</b> expressed as tertiary amine <b>Fat-reduction factor:</b>	0,011 %	Method= (1) <b>(Migration results:</b> -)
<b>FCM:</b> 661 <b>EEC ref:</b> 95360 <b>CAS:</b> 0027676-62-6 <b>Substance name:</b> 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	<b>SML:</b> 5 mg/kg	<b>Fat-reduction factor:</b> yes	0,833 ppm	Method= (1) <b>(Migration results:</b> -)
<b>FCM:</b> - <b>EEC ref:</b> - <b>CAS:</b> - <b>Substance name:</b> Group 23	<b>SML:</b> 6 mg/kg	<b>SML(T) Remark:</b> expressed as methacrylic acid <b>Fat-reduction factor:</b>	6,000 ppm	Method= (1) <b>(Migration results:</b> -)
<b>FCM:</b> 433 * <b>EEC ref:</b> 68320 <b>CAS:</b> 0002082-79-3 <b>Substance name:</b> octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	<b>SML:</b> 6 mg/kg	<b>Fat-reduction factor:</b> yes	15,644 ppm	Method= (1) <b>(Migration results:</b> -)

**Legenda screening methods:**

(1) 100% migration calculation, (2) Overall migration test, (3) Migration modelling, (4) Migration testing, (5) Other

**6. B. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals**

Name / Element	Restriction Screening method	Maximum concentration IN FILM	Migration result
Aluminium "	SML: 1 mg/kg	6,049 ppm	100% migration calculation

In addition, the film itself or comparable film grades have been tested for specific migration of metals listed in Annex II, table 1. The limits of the substances listed in Annex II, table 1 not indicated above are not exceeded.

Test conditions: 3% acetic acid (worst case simulant) during 10 days at 60C.

**6. C Limits and restrictions of non-listed substances**

This product does not contain non-listed substances with restrictions.

**6. D Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines** This Product does intentionally contain Primary Aromatic Amines according to Annex II: NO

**6. E Compliance confirmation**

This Product complies with the limits and restrictions in points 6A, 6B and 6C within this document, based on worst-case calculations, migration modeling or migration testing.

Specific migration is tested under the following conditions: There are no specific migration tests performed on this Product.

**i. Substances listed in Regulation (EU) No 10/2011, Annex I** All substances comply with the applicable limitations.

**ii. Substances listed in Regulation (EU) No 10/2011, Annex II, Metals** All metals comply with the applicable limitations.

#### 7. DUAL USE ADDITIVE(S)

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

Number (E or FL)	Name	Maximum concentration IN FILM
E 330	Citric acid	1,944 ppm
E 470b	Magnesium salts of fatty acids	18,813 ppm
E 551	Silicon dioxide	64,800 ppm
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)	0,061 %

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

## **8. SPECIFICATIONS FOR USE**

### **Specifications of use as regards of type or types of food**

All types of food: aqueous acidic and alcoholic foods (up to 10% alcohol) and foods that

contain fats and oils. **Specifications for use as regards of time and temperature of**

### **treatment and storage of food**

Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where  $70\text{ }^{\circ}\text{C} \leq T < 100\text{ }^{\circ}\text{C}$  for a maximum of  $t = 120/2^{((T-70)/10)}$  minutes.

### **Any other limitations of use**

Ratio of food contact surface area to volume used to establish the compliance of the material or article:  $6\text{ dm}^2/\text{kg}$  food.

## **9. FUNCTIONAL BARRIER**

This Product contains a functional barrier:  
NO

## **10. ADDITIONAL INFORMATION**

This product contains no substances for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding  $0,00015\text{ mg/kg}$  food or food simulant.

### **Legend**

\* Substances marked with a single asterisk in this document are reportable substances with variable concentrations due to variations in supply source.

This document is based on information given to us by our own suppliers by the date of this document and assessed with the best of our knowledge; it is valid only for products as described and delivered by us. It applies for use under normal or foreseeable conditions and does not represent a warranty as to merchantability or fitness for any particular application; it is the customer's responsibility to verify that the final packaging as printed, laminated, slit, treated or converted in any other way after our delivery is in compliance with any applicable legislation.

The information included in this document is valid from the stated issue date until this document is superseded. We review by defaults our declaration every two years. Because of possible changes in the underlying legislation and regulations, as well as possible changes in this Product, we cannot guarantee that the status of this document will remain unchanged. It will be renewed in all cases where the previous conformity is no longer ensured.



## PFAS Declaration:

ECHA has notified a consultation on the use of PFAS (per- and polyfluorinated alkyl substances): <https://echa.europa.eu/de/-/five-european-states-call-for-evidence-on-broad-pfas-restriction>

This is a step in the direction of further PFAS restrictions in Annex XVII of the REACH Regulation and could mean a disruption in some materials used for formulating our products or used in our manufacturing process.

In the context of this consultation, **PFAS are defined very broadly as any chemical substance or polymer that contains at least one aliphatic –CF<sub>2</sub>– or –CF<sub>3</sub> element.**

We ask for your help in providing the information requested in the consultation. At this moment, we would like to raise the following questions to you:

1. Are any substances or polymers used or present in your product(s) supplied to us that contains –CF<sub>2</sub>– or –CF<sub>3</sub>? If yes, please identify them by chemical name, CAS number and EC number.

Supplier answer: Hexafluoropropylene (CAS # 116-15-4)

1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene (CAS # 25190-89-0)

2. List your product(s) supplied to us that contain the substance(s) or polymer(s) identified under point 1 and indicate the concentration in the product.

Supplier answer: - Hexafluoropropylene (CAS # 116-15-4) is used in grades UBWES (max concentration

0.01 ppm) and MU842 (max concentration 11.2 ppm).

- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene (CAS # 25190-89-0) is used in grades GNR, GPR, ETR, ELR, EUH, EUP, LWD, LHD and VLD (max. concentration 5 ppm)
- Fluoropolymer (monomers hexafluoropropylene (CAS # 116-15-4) and vinylidene fluoride (CAS # 75-38-2)) is used in XE447, XE400, XM344 (max. concentration 10 ppm)

3. Will you participate in the consultation specifically with data on the hazards and environmental persistence of these substances or polymers or will you ask your suppliers to do so?

Supplier answer: No

4. What is the technical function of the substances or polymers identified under point 1?

Supplier answer: Residual monomer + production aid

5. Do you have information on the residual concentration, the migration or the release of the identified substances or polymers in their intended uses? Do you have analytical methods available for these investigations?

Supplier answer: testing on-going for Hexafluoropropylene (CAS # 116-15-4) - specific migration testing with food simulant B, PN-EN 13130-1:2006

6. Is the product you are supplying depending on the use of PFAS-related substances or materials (e.g. machinery parts, lubricants, ...) used in your manufacturing process?

Supplier answer: No, the PFCs mentioned above are part of the raw materials used.

7. What could be the impact on your business if certain PFAS are restricted?

Please bear in mind that PTFE, for example, would also fall under the above definition.

Supplier answer: reformulation of certain film grades

8. Are you aware of non-fluorinated alternatives to the PFAS-containing substances or polymers present in your product or used in its manufacturing process? What would be the technical and commercial implications of substitution by PFAS-free materials, and in what timeframe could it be achieved?

Supplier answer: no, we would have to work on the reformulation of certain film grades

It is the customers responsibility to verify the suitability for his intended use.

**Cardboard disclaimer:**

Roll material: If the product is wound on rolls with cardboard cores, the 5 last windings closest to the core are to be discarded. The outside 2 windings of the rolls are to be discarded as well.

Sheet material: If the product has cardboard supports the 5 sheets closest to the cardboard are to be discarded.

Date of issue: 26/04/22

Issuer

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