Declaration of Compliance for Materials and Articles intended to come into contact with Food

On behalf of: Massilly France; FRANPAC; IBEREMBAL; GRUMETAL; MASSILLY INDIA PACKAGING, Massilly Maroc
as the manufacturer

Article	Diameter (mm)	Profiles	Internal lacquer(s)	Compound
Closure	Any diameters	Any profiles	1/2/3 WHBN	P27

1. Material description (from the inner to the outer layer)

- Compound: P27 (PVC; Pasteurisable)
- Internal lacquer(s) : BPA NI (BN), PFAS NI
- Tinplate (absolute barrier)
- Size coating or stoving enamel when applicable BPA NI, PFAS NI
- Inks when applicable BPA NI, PFAS NI
- External lacquer BPA NI, PFAS NI

2. Legal compliance

The article covered by this declaration of conformity complies with the requirements of the following legislation as amended to date:

A. European legislation

- Framework Regulation (EU) No 1935/2004 of 27th October 2004 on materials and articles intended to come into contact with food
- Regulation (EU) No 2023/2006 of 22nd December 2006 on GMP (Good Manufacturing Practice for materials and articles intended to come into contact with food)
- Plastic materials: Commission regulation (EU) No 10/2011 of 14th January 2011 on plastic materials and articles intended to come into contact with food (as amended to date) (for the sealing compound only)
- Regulation (EU) No 1895/2005 of 18th November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food
- Regulation (EU) No 2024/3190 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonised classification for specific hazardous properties

in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) No 2018/213
- European Directive 78/142/EEC relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs
- Directive 94/62 EC Art 11 on packaging and packaging waste (Concentration levels of heavy metals present in packaging)

Furthermore, all starting substances of the dry film used in the formula of the internal coatings are permitted for use according to the CoE Resolution AP(2004)1, CoE Resolution AP(92)2 and according to the CEPE Code of Practice Annex II and III.

Active or intelligent materials as defined in Regulation (EC) No 450/2009 are not intentionally added in the formula of the interior protective coatings or the sealing gasket.

Allergens as defined in the Regulation (EU) No 1169/2011 Art 9.1c are not intentionally added in the formula of the interior protective coatings or the sealing gasket.

Nanomaterials as defined in the Recommendation (UE) No 2022/C 229/01 are not intentionally added in the formula of the interior protective coatings or the sealing gasket.

The articles covered by this declaration are not manufactured using recycled plastics. The Regulation (EC) No 2022/1616 is therefore not applicable.

The Regulation (EU) No 528/212 concerning the making available on the market and use of biocidal products is not applicable.

B. National legislation

- French law : n°2012-1442 of 24th December 2012
- Decree 2007-766 and its amendments, including the decree 2008-1469
- Decree of June 28, 1912 and its amendments on the coloring, preservation and packaging of foodstuffs
- French law 2020- 105 Art 112 (AGEC law on the ban of use on mineral oils on packaging)
- French law 2020-105 Art 13.1 & 13.2 (AGEC law on consumer's information about the SVHC): please refer to the document "Attestation on AGEC law art 13.1 and art 13.2"
- Dutch law: Warenwet, Chapter X, for the coatings
- Spanish Real Decreto 847/2011, for the coatings
- Italian Decreto Ministeriale 21/3/1973, for the coatings
- US law: FDA code of federal regulations 21CFR§175300 (internal coatings) and 21CFR§1771210 (Closures with sealing for food containers)
- State legislation in the USA prohibiting the intentional use of PFAs in food packaging

- Japan, Food Sanitation Act Notice N°370 Annex 1 of positive list for substances to manufacture food contact materials: in compliance with the positive list as applicable starting June 1st 2025
- The printing inks used on the non food contact side (if applicable) are in compliance with the Swiss ordinance 817.023.21, Annex 10

C. Recommendations and guidelines:

- BfR-Recommendations on Food Contact Materials
- The tinplate used meets the compositional requirements of the EN 10333/ 10334 and EN610
- MPE guidelines (good manufacturing practices)
- SNFBM good manufacturing practice guide
- CEPE Code of Practise
- EuPIA Guideline on printing inks applied to food contact materials if applicable
- EuPIA Exclusion Policy for printing inks if applicable
- EuPIA Suitability list for photoinitiators if applicable

3. Food contact conditions

This declaration of compliance has been established in respect of the following:

A. Type of foodstufft:

With the exclusion of baby food, the article is suitable for single use and for contact with:

- moist foods / aqueous foods
- fatty foods
- acidic foods

This section only relates to contact ability without surface, volume, or quantity considerations. Please refer to the supporting documentation to verify the minimum surface and volume requirements depending on the diameter.

B. Pack process conditions

- Hot fill up to 100°C or cold fill followed by heat treatment up to 100°C – 1H followed by long term storage above 6 months at room temperature

C. Global and Specific Migrations

- The food business operator shall assess the food category where its food product belongs in order to select the appropriate simulant(s) (cf. Regulation (EU) No. 10/2011, Annex III, Table 2). The corresponding ratio between surface in contact with foodstuffs and volume must be respected, as well as the minimum filling volumes and/or weights indicated in document "**P27 migration supporting documentation**".

4. Information on substances with restrictions

A. Compliance of substances (monomer/ starting substances/ additive) having a restriction

To our best knowledge, based on the information received from our suppliers, the following starting substances with restrictions are used in the formula of the internal coatings and sealing compound:

- Lacquer:

Name of substance	**CAS N°**	**PM ref. N°**	**Restriction [Resolution AP(2004)1]**
Adipic acid	124-04-9	12130	SML= 60 mg/kg
Acetic acid, vinyl ester	108-05-4	10120	SML=12 mg/kg
2- Methyl-1.3-propanediol	2163-42-0	22190	SML = 5 mg/kg
Diethylenglycol	111-46-6	15760	SML(T) = 30 mg/kg
Ethylene Glycol	107-21-1	16990	SML(T) = 30 mg/kg
1,1,1-trimethylolpropane	77-99-6	25600	SML = 6 mg/kg
1,4-Butanediol	110-63-4	13720	SML(T) = 5 mg/kg
1,2- Dihydroxybenzene	120-80-9	15880	SML = 6 mg/kg
2,2-Dimethyl-1,3-propane diol	126-30-7	16390	SML = 0.05 mg/kg
Tricyclodecanedimethanol	26896-48-0	25450	SML = 0.05 mg/kg
Terephthalic acid	100-21-0	24910	SML = 7.5 mg/kg
Isophthalic acid	121-91-5	19150	SML = 5 mg/kg
Acids, fatty, unsaturated (C18), dimmers, hydrogenated, non distilled	68783-41-5	10559-93	QMA(T) = 0.05 mg/6 dm²
Isophorone di-isocyanate	4098-71-9	19110	QM (T) = 1 mg/kg in FP (as NCO) SML(T) = ND as NCO
Caprolactam	105-60-2	14200	SML(T) = 15 mg/kg
Trimellitic anhydride	552-30-7	25550	SML(T) = 5 mg/kg (as trimellitic acid)
Phenol	108-95-2	22960	SML= 3 mg/kg
Acetaldehyde	75-07-0	10060	SML (T) = 6 mg/kg
Caprolactone	502-44-3	14260	SML = 0.05 mg/kg (as the sum of caprolactone and 6-hydroxyhexanoic acid)
Isophtalic acid, dimethyl ester	1459-93-4	19210	SML = 0.05 mg/kg
Vinyl chloride	75-01-4	26050	QM = 1 mg/kg in FP SML = ND (DL = 0.01 mg/kg)
Sorbitan monolaurate	1338-39-2	87600	SML = 300 mg/kg

2,6-Di-ter-butyl-p-cresol (=BHT)	128-37-0	46640	SML = 3 mg/kg
Fumaric acid	110-17-8	17290	SML = 360 mg/kg
Aluminium	7429-90-5	-	SML = 1 mg/kg
Aluminium oxide	1344-28-1	37420	SML = 1 mg/kg (as Al)
Monobutyltin tris(2-ethylhexanoate)	23850-94-4	-	< 10 µg/kg
Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	-	95859	-

Based on a max S/V ratio of 6dm²/1 kg of food, the compliance with the substances with restriction has been assessed and confirmed by a 3rd party laboratory either by migration testing (1h130+ 10d 60°C) , extraction testing or worst case calculation. For each substance, the most severe condition has been chosen. The ratio to be taken into consideration is the surface of the closure to the filling weight of the foodstuff.

- Sealing Compound

Name of substance	**CAS number**	**PM ref. No**	**Restriction**
Vinyl chloride	75-01-4	26050	QM = 1 mg/kg in FP SML = ND (DL = 0.01 mg/kg)
9,10- dihydroxystaeric acid	-	48960	SML= 5 mg/kg
Epoxidised soy bean oil	8013-07-8	888640	SML= 60 mg/kg (group 32)
Dibutylsebacate (DBS)	109-43-3	85360	SML= 60 mg/kg (group 32)
Formaldehyde-1-naphthol, copolymer	25359-91-5	54930	SML= 0.05 mg/kg
Sodium nitrite	7632-00-0	96920	SML= 0.6 mg/kg
Zinc	-	-	SML= 5 mg/kg (Annex II)

B. <u>List of dual use additives</u>

	Name of Additive	**CAS N°**	**PM/REF N°**
E250	Sodium nitrite	7632-00-0	96920
E321	2,6-Di-ter-butyl-p-cresol (=BHT)	128-37-0	46640
E355	Adipic acid	124-04-9	12130
E297	Fumaric acid	110-17-8	17290
E493	Sorbitan monolaurate	1338-39-2	87600

E551	Silicon dioxide	7631-86-9	86240
E464	Methylhydroxypropylcellulose	9004-65-3	66700
E900	Polydimethylsiloxane	63148-62-9	76721

5. Information on others substances

A. Phthalates

- Phthalates (such as for example DEHP, DIDP, DINP etc) are not intentionally used in the formula of the internal coatings nor in the formula of the sealing compound.

B. Bisphenols

- The “BPA- NI” coatings are not manufactured using intentionally Bisphenol A (CAS 80-05-7), or with any materials made from Bisphenol A.
- The bisphenols (as listed below) are not intentionally added in the formula of the internal coating nor in the formula of the sealing compound:
  Bisphenols*:

Denomination	CAS N°
Bisphenol AP	1571-75-1
Bisphenol AF	1478-61-1
Bisphenol B	77-40-7
Bisphenol BP	1844-01-5
Bisphenol C	79-97-0
Bisphenol C2	14868-03-2
Bisphenol E	2081-08-5
Bisphenol F	620-92-8
Bisphenol FL	3236-71-3
Bisphenol G	127-54-8
Bisphenol P	2167-51-3
Bisphenol PH	24038-68-4
Bisphenol S	80-09-1
Bisphenol TMC	129188-99-4
Bisphenol Z	843-55-0

C. Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH)

- Mineral Oil Aromatic Hydrocarbons (MOAH) are not intentionally used in the formula of the coatings and sealing compound used in this article.
- However some coatings may contain some lubricants which are made from hydrocarbon waxes and therefore may contain traces of Mineral Oil Saturated Hydrocarbons (MOSH).
- The printing inks used on the metal packaging are not formulated from MOSH or MOAH nor from substances containing MOSH or MOAH.

D. Carbon black

- Carbon black is not intentionally added in the formula of the internal coating nor in the formula of the sealing compound.
- Carbon black may only be present if a black ink is used for decoration on the external side.

E. Titanium Dioxide

- Titanium dioxide is added in the formula of the internal coating and sealing compound.

F. Non-Intentionally-Added-Substances (NIAS)

- Not yet practicable- work in progress by the EU authorities and the supply chain.

G. Ingredients of animal origin or alcohol derivated

- Based on the information provided by our suppliers, no raw material of animal origin or alcohol origin, is used in the formula of the internal coating nor in the formula of the sealing compound.
- No lubricants of animal or alcohol origin are intentionally added during the manufacturing process.
- With regard to the conditions of the production process and the raw materials used, the article meets the requirements of Halal Islamic law, Kosher and vegan.

H. Genetically Modified Organism (GMO)

- Based on the information provided by our suppliers, no GMOs are intentionally added in the formula of the interior coatings, nor in the formula of the sealing compound.

6. Environment

A. Environmental requirements

- The articles are in compliance with articles R.543-42 to R.543-52 of the French Environment Code.
- The articles are manufactured in compliance with the following relevant CEN standards when applicable
    - Prevention by reduction at source (EN 13428) – (Art.543-44 1): Yes
    - Re-usage (EN 13429) – (Art.543-44 2): Not applicable
    - Substance recycling (EN 13430) – (Art.543-44 2): Yes
    - Energy re-processing (EN 13431) – (Art.543-44 2): Not applicable
    - Processing through composting and bio-degradation (EN 13432) – (Art.543-44 2): Not applicable
    - Dangerous substances : attestation of minimization – (Art. R543-44c): Yes
    - Heavy metals: Attestation of Respect of Regulatory Limits – (Art. R543-45): Yes

B. Recyclability

- Metal is a permanent material which can be recycled forever without losing its properties.
- The proportion of recycled steel incorporated in the manufacture of steel in Europe, all purposes included, is **58.2%** in 2022. (source BIR World Steel Recycling in figures 2018-2022 (link https://www.bir.org/publications/facts-figures)).

- To the best of our knowledge, the raw materials used in the manufacturing of our packaging other than the metal, are not manufactured from recycled or renewable materials.

15.01.2025

Author:
Cyrielle BENIFEÏ
Regulatory affairs specialist

Approval by:
Véronique MONNERAYE
Group R&D Raw Materials Manager

VALIDITY

This Declaration of Compliance is valid for a 5 years period as from signing date thereof.
NB: The DoC shall be updated when substantial changes in the production bring about changes in the migration or when new scientific data are available. The latest version of the DoC supersedes any previous one established for the same materials or articles.

DISCLAIMER

Pursuant to Regulation EC No 178/2002, the food business operator is liable for the suitability of packaging material for the food production, processing and distribution, and to assess compliance with the regulations mentioned in chapter 2° hereof, while organoleptic characteristics' preservation and limitation of effective migration from the caps depend on various factors which are beyond Massilly's control, such as composition, processing, heat treatment, storage conditions, etc.

Therefore declaration of compliance hereby is only related to the herein specified caps before use, with no warranty, whether expressed or implied, regarding the compliance of any subsequent packed food or food business.

Regarding migration limits, conformity herewith results from laboratory simulations as defined by Regulation EU No 10/2011;art. 18.6 thereof provides however that specific migration's values obtained in food shall prevail. Therefore the food business operator is liable to ascertain that actual migrations don't excess regulatory limits throughout the product shelf life, and it is hereby strongly advised by Massilly to perform any supporting testing.