

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

On behalf of: Massilly France; GRUMETAL; MASSILLY INDIA PACKAGING
as the manufacturer

Article	Diameter (mm)	Profiles	Internal lacquer(s)	Compound
Closure	Any diameters	Any profiles	1/2/3 WHBN	P56

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

- Compound: P56 (PVC NI pasteurized,)
- Internal lacquer(s) : BPA NI (BN) PVC NI, PFAS NI
- Tinplate (functional barrier)
- Stoving enamel or size coat 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 when applicable:

A. European regulation

- 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
- 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 regulation

- 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 Practice
- 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 foodstuff:

With the exclusion of baby food, the article is suitable for single use 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 “**P56 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 number	PM ref. No	Restriction [Resolution AP(2004)1]
1,6- Hexanediol	629-11-8	18700	SML= 0.05 mg/kg
Adipic acid	124-04-9	12130	SML=60 mg/kg
2,4-diamino-6-phenyl-1,3,5-triazine	91-76-9	15310	QMA= 5mg/6dm ²
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
Hexahydroterephthalic acid	1076-97-7	18444	SML = 5 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
Terephthalic acid, dimethyl ester	120-61-6	24970	SML = 60 mg/kg
Maleic anhydride	108-31-6	19960	SML(T) = 30 mg/kg (as maleic acid)
Acids, fatty, unsaturated (C18), dimmers, hydrogenated, non distilled	68783-41-5	10559-93	SML(T) = 0.05 mg/kg
Titanium(IV) (triethanolaminate)isoprop oxide	74665-17-1	-	SML = 5 mg/kg AP(92)2
1-isocyanato-3-isocyanato methyl-3,5,5-trimethylcyclo hexane	4098-71-9	19110	QM (T)= 1 mg/kg (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)
Phosphoric acid	7664-38-2	23170	SML=4200mg/kg
4-ter-butylphenol	98-54-4	14020	SML= 0.05 mg/kg
2,6-Di-tert-butyl-p-cresol	128-37-0	46640	SML = 3 mg/kg
Phenol	108-95-2	22960	SML= 3 mg/kg
Aluminium	7429-90-5	-	SML = 1 mg/kg
Aluminium oxide	1344-28-1	34720	SML = 1.0 mg/kg (Al)
Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks.	-	95859	-
Hydrogen peroxide	7722-84-1	-	SML = 0,05 mg/kg (as O)
Quaternary ammonium compounds	-	-	SML = 0,5 mg/kg

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 Nr	PM Ref Nr FCM Nr	Restriction
N,N-bis(2-hydroxyethyl) alkyl(C8-C18)amine	-	39090 FCM19	SML(T) = 1,2 mg/kg
N,N-bis(2-hydroxyethyl) alkyl (C8-C18)amine hydrochlorides	-	39090 FCM20	SML(T) = 1,2 mg/kg excluding HC
1,1,1-Trimethylolpropane	77-99-6	13380 FCM141	SML = 6 mg/kg
Butadiene	106-99-0	13630 FCM223	SML = ND
1-Octene	111-66-0	22660 FCM264	SML = 15 mg/kg
Octadecyl 3-(3,5-Di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	68320 FCM433	SML = 6 mg/kg
9,9-Bis(methoxymethyl)fluorene	182121-12-6	39815 FCM779	SML=0.05 mg/kg
undisclosed substances*			SML = 4.8 mg/kg
undisclosed substances*			SML = 0.05 mg/kg
undisclosed substances*			SML = 5 mg/kg

*The identity of the substances is kept confidential by the supplier. However they have been assessed and the conformity has been certified by a 3rd party laboratory up to a S/V ratio of the closure only up to 6.

Furthermore the supplier indicates the following compounds falling under the annex II of the Regulation (EU) No 10/2011: Aluminium, Zinc, Iron and Lithium.

B. List of dual use additives

	Name of additive	CAS number	PM ref No
E927b	Urea (carbamide)	57-13-6	93440
E470a	Sodium, potassium and calcium salts of fatty acids	-	89040
FL 01.070	1-Octene	111-6-0	22660
E553b	Talc	14807-96-6	92080
E321	2,6-Di-tert-butyl-p-cresol	128-37-0	46640
E355	Adipic acid	124-04-9	12130
E297	Fumaric acid	110-17-8	17290
E422	Glycerol	56-81-5	18100
E338	Phosphoric acid	7664-38-2	23170
E900	Polydimethylsiloxane	9016-00-6	76721
E551	Silicon dioxide	7631-86-9	86240

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:

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

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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)

- NIAS may be present as impurities in raw materials or as a result of the manufacturing or application processes. NIAS with a molecular weight (MW) above 1000 daltons (Da) are unlikely to be absorbed by the gastrointestinal tract and thus are not considered to present a toxicological risk. (EFSA CEP Panel 2008). Consequently, only NIAS with a molecular weight below 1000Da were considered in the risk assessment. A tentative identification has been performed for substances migrating above a threshold of 0.01mg/6dm². The standard S/V ratio of 6 has been used for the risk assessment.
- For the lacquer, the non-target screening of the migrate for non-volatile components was conducted in simulant 95 % ethanol for 4h at 60°C + 10d 60°C or in acetonitrile for 24h at room temperature. The analytical results show peaks > 0.010 mg/kg of substances identified as belonging to the polyester family or isocyanates used in the formula of the interior protective coating. Unknown substances were also detectable. Based on the information received from our supplier, genotoxicity can be ruled out. Assuming a standard consumption of 1kg of food per day, the ADI of the identified substances will not be exceeded and an exposure above the TTC threshold of Cramer class III is unlikely for the unknown substances. There is no evidence for health concerns or reasons which would interfere with the compliance with the article 3 of the Framework Regulation (EU) No 1935/2004.

- For the sealing compound, the non-target screening of the migrate for semi-volatiles components was conducted in simulant 95 % ethanol for 10d 60°C. Based on the S/V ratio of 50 cm²/kg of food, 14 substances were identified above the threshold of 10ppb/kg. None of them were assessed to give reason for health concern or which would interfere with the compliance with the article 3 of the Framework Regulation (EU) No 1935/2004
- This information is based on the present state of our knowledge of current legislation and standards.

G. Ingredients of animal origin or alcohol derived

- 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.

28.02.2025

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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.