

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

On behalf of: Massilly France SAS; FRANPAC; IBEREMBAL; GRUMETAL

Article	Diameter (mm)	Profiles	Internal lacquer(s)	Compound
Closure	43, 53 and 70	All profiles : RTO; RTB; RSB; RTS; RTA; RAB; FAO; FAB; FAS ; FSB; TNV; TNB	1/2/3 WH	P25

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

- Compound: P25 (PVC; Pasteurisable)
- Internal lacquer(s) : BPA NI (BN)
- Tinplate (functional barrier)
- Inks when applicable
- External lacquer

2° Legal compliance (where applicable)

The article covered by this declaration of conformity complies with the requirements of the following legislation when applicable:

A) European regulation

- Framework Regulation (EC) No 1935/2004 of 27th October 2004 on materials and articles intended to come into contact with food.
- Regulation (EC) 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 sealant only)

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- Regulation (EU) No 2018/213 relative to the use of BPA in vanished and coatings intended to come into contact with food.
- European Directive 78/142/EEC on Vinyl Chloride
- All starting substances of the dry film used in the formula of the internal coating 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.
- Regulation (EC) 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.
- CONEG- 94/62 EC Art 11

B) National regulation

- French law : n°2012-1442 of 24th December 2012
- Décret 2007-766 and its amendments, including the décret 2008-1469
- US law: FDA code of federal regulations 21CFR§175300 (internal coatings) and 21CFR§1771210 (Closures with sealing for food containers)
- Dutch law: Warenwet (coatings), Chapter X
- Spanish Real Decreto 847/2011 (coatings)
- German LFGB §§ 30 and 31(1) , for the coatings
- Italian Decreto Ministeriale 21/3/1973 (coatings)
- Belgium royal decree of 25.09.2016 (Art. 4 et 5), for the coatings

C) Recommendations and guidelines:

- BfR-Recommendations on Food Contact Materials
- EN 10333
- MPE guidelines (good manufacturing practices)
- SNFBM good manufacturing practice guide

3° Food contact conditions

A) Type of foodstuff:

- Contact with moist foods / aqueous foods
- Contact with fatty foods
- Contact with acidic foods

This section only relates to contact ability without surface, volume, or quantity considerations: beware of the minimum container volume resulting from migration simulation, under which the closure must not be used, depending on the kind of food products, especially oily/fatty foodstuffs.

B) Pack process conditions

- heat treatment: 100°C – 1H

C) Global and Specific Migrations

- Ratio of food-contact surface area to volume and minimum filling volumes obtained with each simulant are respectively specified in the relevant attached laboratories reports.
- Migration simulation tests were performed pursuant to Regulation (EU) No 10/2011 (Annex V) with mandatory food simulants thereof (Annex III)
- The Food business operator shall assess the food category where its food product belongs to in order to select the appropriate simulant(s) (cf. Regulation (EU) No. 10/2011, Annex III, table 2) and comply with the corresponding ratio of food-contact surface area to volume and minimum filling volumes and/or weight as indicated in the migration testing reports.
- Depending on the food category, the Food Business Operator may divide the migration test result (i.e. increase the minimum filling volume) with the correction factor provided for in sub-column D2 of column 3 of Table 2 of Annex III of Regulation (EU) No 10/2011.

Closure reference	Laboratory report reference
43 P25	43-P25-PAST-EF-0538-15-6
53 P25	53-P25-Past-EF-0216_FPM_FDC_16_1
70 P25	70-P25-TNB-TNV-PAST-1398_14_1

D) List of substances (monomer/ starting substances/ additive) having a restriction

Lacquer:

Name of substance	CAS number	PM ref. No	Restriction [Resolution AP(2004)1]
Diethyleneglycol	000111-46-6	15760	SML(T)= 30 mg/kg
Ethyleneglycol	000107-21-1	16990	SML(T)= 30 mg/kg
2-Methyl-1, 3-propanediol	002163-42-0	22190	SML = 5 mg/kg
1,4-Butanediol	000110-63-4	13720	SML(T)= 5 mg/kg
2,2-Dimethyl-1,3-propane diol.	000126-30-7	16390	SML = 0.05 mg/kg
Tricyclodecanedimethanol	026896-48-0	25450	SML = 0.05 mg/kg
Terephthalic acid	000100-21-0	24910	SML = 7.5 mg/kg
Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester		25360	QM=1 mg/kg FP (as epoxy group Mw=43)
Tricyclodecanedimethanol	26896-48-0	25450	SML= 0.05mg/kg
Terephthalic acid, dimethyl ester	000120-61-6	24970	SML= 60mg/kg
Acetic acid, vinyl ester	000108-05-4	10120	SML= 12mg/kg
1,2-Dihydroxybenzene	000120-80-9	15880	SML=6mg/kg

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Adipic acid	000124-04-9	12130	SML= 60mg/kg
Isophthalic acid	000121-91-5	19150	SML = 5 mg/kg
Trimellitic anhydride	000552-30-7	25550	SML(T) = 5 mg/kg (as trimellitic acid)
Caprolactam	000105-60-2	14200	SML(T)=15mg/kg
1,-Isocyanato-3-isocyanato methyl-3,5,5-trimethylcyclo hexane	0004098-71-9	19110	QM(T)= 1 mg/kg as NCO
Acids, fatty, unsaturated (C18), dimmers, distilled	061788-89-4	10559-90A	QMA(T) = 0.05 mg/6 dm ²
Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstock		95859	
Vinyl chloride	000075-01-4	28050	QM = 1 mg/kg in FP
Tetrafluoroethylene	000116-14-3	25120	SML=0.05 mg/kg
2,6-Di-ter-butyl-p-cresol (=BHT)	000128-37-0	46640	SML= 3mg/kg
Monobutyltin tris(2-ethylhexanoate)	0025850-94-4		SML=<10ppb according to CEPE CoP art 3
Phenol	000108-95-2	22960	SML= 3 mg/kg

Sealing Compound

Name of substance	CAS number	PM ref. No	Restriction
Vinyl chloride	000075-01-4	26050	SML = ND mg/kg QM ^{<} 1 mg/kg in finished product
9,10- dihydroxystaeric acid		48960	SML= 5mg/kg
tri n-butyl- acetil –citrate (ATBC)	77-90-7	93760	SML= 60 mg/kg (group 32)
Dibutylsebacate (DBS)	109-43-3	85360	SML= 60 mg/kg (group 32)
Polyester of 1,2 propane diol and/or of 1.3 and/or 1.4 butanediol and/or propylenglycol with adipic acid		73	SML= 60 mg/kg (group 32) SML= 30mg/kg (group 31)
Zinc			SML= 5mg/kg (Annex II)

E) List of dual use additives

	Name of Additive	PM/REF N° and/or CAS N°
E365	Adipic acid	CAS 124-04-9 / Ref 12130
E321	2,6-Di-ter-butyl-p-cresol (=BHT)	CAS 000128-37-0
FDA 172.615	Lanolin	CAS 008006-54-0
E422	Glycerol	CAS 000056-81-5
E1520	1,2 propanediol	CAS 57-55-6
E171	Titanium dioxide	CAS 13463-67-7/ Ref 610
FL-09-511	tri n-butyl- acetil-citrate (ATBC)	CAS 77-90-7/ Ref 93760
E900	Polydimethylsiloxane	CAS 63148-62-9 / Ref 76721
	Stearic acid & derivatives	CAS 57-11-4 / Ref 24550/89040
	Carbonic acid & salts	Ref 42500
	Silicon dioxide, citric acid & salt	CAS 7631-86-9 / Ref 82240

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

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

G) Active and intelligent material- Regulation (EC) No 450/2009 of 29th May 2009

- not included

H) Recycled plastics- Regulation (EC) No 282/2008 of 27th March 2008

- not included

18 August 2020

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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.