

## DECLARATION OF COMPLIANCE

Company	TECNOCAP
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### Subject: Tecnocap caps (range: from 33mm to 110mm) lined with compound mod TPE (pasteurisation process)

The caps in subject are suitable for:

- Condition of use: heat treatment of pasteurisation, up to 100°C for 1h, and shelf life up to **36 months**.
- Food category: Products listed in Annex to Commission Regulation (EU) N° 10/2011 and its amendments with **exception of fatty foods or containing oil**.

TECNOCAP, with regard to the subject, declares that:

#### *1. – Requirements and Legislation*

TECNOCAP S.p.A., with regard to the subject, declares that:

- All the caps of its production are suitable and hygienically safe for the sealing of glass jars for alimentary use, when these are filled and processed correctly.
- Tecnocap caps comply with Regulation (EC) N° 1935/2004; (EC) N° 2023/2006, (EC) N° 94/62, (EC) N° 1895/2005 FDA 21CFR 175.300 and Commission Regulation (EU) 2018/213 of 12 February 2018.
- Plastic materials, as compound, comply to the Commission Regulation (EU) N° 10/2011 and its amendment.

- Electrolytic tinplate used is in compliance with EN 10202:2011 and D.M. 21/03/1973
- Tecnocap compounds are free from phthalates and adipates (DEHA), 2-EHA (Acid 2-ethylhexanoic) and Semicarbazide.
- Tecnocap caps, if provided with lacquering system BPAni, comply with the following legislation regulating food contact:
  - *FDA ( 21CFR 175.300)*
  - *EC Regulation N° 1935/2004*
  - *The epoxy regulation N° 1895/2005/EC*
  - *The CEPE "CODE OF PRACTICE FOR COATED ARTICLES WHERE THE FOOD CONTACT LAYER IS A COATING"*
  - *D.M. 21/03/73 and following updates*
  - *Bekendtgørelse Nr. 515 af 18. maj 2010 (Danish regulation)*
  - *French Law 2012-1442 (voted on 24<sup>th</sup> Dec 2012)*
  - *Belgian Position: Act of 4<sup>th</sup> Sept 2012 on food contact material for children up to the age of 3*

### 1.1 Secret information

The following substances of compound are subject to Specific Migration Limits (SML) and/or restriction or specification in Reg. 10/2011/EC

CAS No.	PM ref.	Name	Restrictions/specifications
000075-01-4	26050	Vinyl Chloride Monomer	1 mg/kg
063148-62-9	76721	polydimethylsiloxane	Specifications in annex I reg. 10/2011/EC
000557-05-1	\	Zinc Stearate	5 mg/Kg (expressed as Zinc)
008013-07-8	88640	Epoxidised Soya Bean Oil	60 mg/kg or 10 mg/dm <sup>2</sup>
0007727-43-7	\	Barium Sulphate	1 mg/kg (expressed as Ba)

The following substances of compound are NO subject to Specific Migration Limits (SML) and/or restriction and specification in Reg. 10/2011/EC

CAS No.	PM ref.	Name	Restrictions/specifications
00301-02-0	68960	Oleamide	
00112-84-5	52720	Erucamide	

The listed substances have No specific restrictions but a generic SML is fixed in 60mg/Kg

The following substances (*dual-use additive*) of compound are NO subject to Specific Migration Limits (SML) and/or restriction and specification in Reg. 10/2011/EC

CAS No.	PM ref.	E-number	Name	Restrictions/specifications
000144-55-8		E500	Sodium bicarbonate	
13463-67-7	93440	E171	Titanium dioxide	
001592-23-0	\	E470a	Calcium Stearate	

## 2. – Experimental part

### 2.1 – Global and Specific migration

A total migration test has been carried out according to the guidelines laid down in Commission Regulation (EU) N° 10/2011 and its amendments.

#### Data for no fatty food

<b>Simulant</b>	Acid Acetic 3% (simulant “B”)
<b>Test Condition</b>	1h at 100°C + 10days at 40°C
<b>Result (from cap size 33mm to 110mm)</b>	< 4mg/cap

<b>Simulant</b>	Ethanol 20% (simulant “C”)
<b>Test Condition</b>	1h at 100°C + 10days at 40°C
<b>Result (from cap size 33mm to 110mm)</b>	< 5mg/cap

<b>Simulant</b>	Water
<b>Test Condition</b>	1h at 100°C + 10days at 40°C
<b>Result (from cap size 33mm to 110mm)</b>	< 2mg/cap

#### Important notes:



- 1) *This Statement of Conformity, with regard of information related to Global and Specific migration, is generated in according to tests carried out from independent and qualified laboratories. Tests realized with simulants are in respect to Commission Regulation (EU) N° 10/2011 and its amendments*
- 2) *As stated in (32) of Commission Regulation (EU) N° 10/2011 and its amendments, at each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the **enforcement authorities**. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming, it should be admissible that compliance can be demonstrated also by calculations, including modelling, others analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing.*
- 3) *Some parameters, like foodstuff ingredients, closing process, volume jar, heat treatment, storage condition of finished product, could influence migration that may result higher.*
- 4) *Fillers and packers have the responsibility to verify that migration values remain within the limits required by the EU regulations. It's also their responsibility to carry out any necessary test to confirm that.*
- 5) *Variability of parameters above reported is not under control of Tecnocap so we cannot be responsible for use condition and process/storage of caps.*
- 6) *Transport selling and invoice document will report caps' production plant.*

Issued: 09/01/2020

Approved: Corporate R&D Manager – M. Coccorese - TECNOCAP



## Tecnocap – Declaration of conformity

Tecnocap S.p.A. declare that the twist cap delivered are in accordance with regulation (UE) N. 10/20111 and FDA 21 CFR 175.300.

Our supplier assurance us that the varnish used are free of the following substances

### **Bisphénols B,M, S, AF, AP ou Bisphénols A diglycidyléther (BADGE)**

**Phtalate BBP (butylbenzyl phtalate)**

**Phtalate DBP (di-butyl phtalate)**

**Phtalate DEHP (di(2-éthylhexyl) phtalate)**

**Phtalate DEP (diéthyl phtalate)**

**Phtalate DIBP (diisobutyl phthalate)**

**Phtalate DIDP (di-iso-décyl phtalate)**

**Phtalate DINP (di-isononyle)**

**Phtalate DMEP (phtalate de di(2-méthoxyethyle))**

**Phtalate DNOP (di-n-octyl phtalate)**

**Phtalate DPEP (dipentyl phtalate)**

**Trioxide d'antimoine**

**PBDE (ethers diphényliques polybromés)**

**Hexabromocyclododécane (HBCDD)**

**4,4'- Diaminodiphenylmethane (MDA)**

**Alkanes, C10-13, chloro - (SCCP)**

The declaration is for the reference that in the article code have **A** in 10<sup>th</sup> position:

Exemples :

63SA10113**A**3-A00 ALVEARE CON API 63-PAST

82SA10125**A**3-A00 ALVEARE CON API 82 RTS - PAST

82SA10069**A**3-A00 CASSETTA API IN PAGLIA 82 – PAST.

82SA15061**A**7-A00 FRUITS & FLEURS RTS 82 - PAST.

63SA10114**A**7-A00 APE SU FIORE ROSA 63-PAST.

82SA10124**A**7-A00 APE SU FIORE ROSA 82-PAST.

63SA10037**A**7-A00 FIORI 4 COLORI 63-PAST.

82SA10041**A**7-A00 FIORI 4 COLORI 82-PAST.

63SA10068**A**3-A00 CASSETTA API IN PAGLIA TO 63-PAST.

82SA10069**A**3-A00 CASSETTA API IN PAGLIA 82 – PAST.

11/02/2014

**Marco Coccoresse**  
**Quality Manager**



metal packaging

### **Information statement: Bisphenol A (BPA)/ Bisphenol S, F and B**

Tecnocap produces metal vacuum closures which, used appropriately, are conform to EC and FDA Food contact regulations.

#### ➤ **Traditional lacquering system epoxy based**

Bisphenol A (CAS nr. 80-05-7) is not intentionally used during manufacturing process/ lacquering process by Tecnocap but is present in some raw material as epoxy and phenolic resins.

The lacquer system used by Tecnocap for internal protection is in compliance with the following legislation and guidelines:

- Regulation EU 2018/213;
- Directive 2004/19/EC (Bisphenol A);
- Regulation (EC) N° 1895/2005 (BADGE; absence of BFDGE and NOGE)
- Code of Practice for coated articles where the food contact layer is a coating (from CEPE)

Epoxyphenolic lacquers are used by Tecnocap as internal protection of caps. Nevertheless, the last layer of lacquer applied on the internal side of caps, which is in contact with food, is Organosol lacquer.

Organosol is completely free by Bisphenol A and is a barrier between epoxyphenolic lacquer and food.

The analysis made on tinplate lacquered with our internal protection (epoxyphenolic lacquer + organosol) show no detectable migration values of Bisphenol A (lower than  $0,5 \mu\text{g} / \text{dm}^2$  (3ppb)).

#### ➤ **BPA<sub>ni</sub> lacquering system**

Since some years systems BPA-not intended (hereinafter “BPA<sub>ni</sub>” systems) are available for Tecnocap caps.

The new generation of BPA<sub>ni</sub> internal protective systems are suitable also for aggressive/acid foods and actually they are commonly supplied to many customers.

#### ▪ **BPS, BPF and BPB**

Finally, for both internal protective systems, Tecnocap confirms that *4,4-dihydroxydiphenylsulfone (bisphenol S CAS N° 80-09-1)*, *4,4'-dihydroxydiphenylmethane (bisphenol F CAS N° 620-92-8)* and *2,2-Bis 4-hydroxyphenyl butane (bisphenol B CAS N° 77-40-7)* are not intentionally used during the manufacturing process and according to our current knowledge is not present into any raw material composing products used by Tecnocap.

Kind Regards

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Approved: Corporate R&D Manager – M Coccoresse