



## **DECLARATION OF CONFORMITY**

Company	TECNOCAP
Address	Via Starza – 84013 – Cava de’ Tirreni (SA) – Italy (Headquarter and Italy plant); Strizovice 67- 378 53 Strmilov, Czech Republic (Cz plant).
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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.
- Plastic materials, as compound, comply to the Commission Regulation (EU) N° 10/2011 and its amendments at document date.

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- 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	25 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 (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

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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

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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 : 08/01/2018

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

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