



DECLARATION OF COMPLIANCE

Company	TECNOCAP
Address	Via Starza – 84013 – Cava de’ Tirreni (SA) – Italy (Headquarter and Italy plant); Strizovice 67- 378 53 Strmilov, Czech Republic (Cz plant).
Quality contact	qualita@tecnocapclosures.com
e-mail	info@tecnocapclosures.com
Web site	www.tecnocapclosures.com

Subject: Tecnocap caps (range: from 48mm to 110mm) lined with compound mod TSR (sterilisation process)

The caps in subject are suitable for:

- Condition of use: heat treatment of sterilisation, up to 125°C for 1h (difference between inside and outside pressure less than 0,7 bar), and shelf life up to **48 months**
- Food category: Products listed in Annex to Commission Regulation (EU) N° 10/2011 and its amendments and **specifically suggested for fatty foods or containing free oil**

TECNOCAP, 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.
- 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*

Tecnocap S.p.A. ITALY

Headquarters

Via Starza · 84013 Cava de’ Tirreni (Salerno)
Tel. +39 089 441522 · Fax +39 089 442585

Tecnocap s.r.o. CZECH REPUBLIC

Strizovice, 67 · 37853 Strmilov · Jindrichuv Hradec
Tel. +420 (0)384 373 111 · Fax +420 (0)384 373 529

Tecnocap UA LLC UKRAINE

Str. Vokzalna, 18 · 80356 Soposhyn - District Zhovkva, Region Lviv
Tel. +38 032 526 19 39 · Fax +38 032 522 23 05

Other facilities: Tecnocap-Met SPAIN · Tecnocap LLC (WV) USA · Tecnocap LLC (OH) USA

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- *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 24th Dec 2012)
- Belgian Position: Act of 4th Sept 2012 on food contact material for children up to the age of 3

1.1 Secret information

The information reported in section 1.1 and in section 2. are disclosed subject to the terms of a Confidentiality Agreement.

For used substances which are subject to a restriction and/or specifications in food or for which purity criteria in accordance Commission Regulation (EU) N° 10/2011 and its amendments, are listed as follows:

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 ²
136155-46-9	76866	Polyesters of 1,2-propanediol and/or 1,3-and/or 1,4-butandiol and/or polypropilenglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C12-C18 or n-octanol and/or n-decanol (Polyadipates)	30mg/Kg or 5mg/ dm ²

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
736150-63-3	55910	Glycerides, castor-oil mono, hydrogenated, acetates	
00077-90-7	93760	Tri-n-butyl acetyl citrate	
000109-43-3	85360	Sebacic acid, dibutyl ester	
00301-02-0	68960	Oleamide	
00112-84-5	52720	Erucamide	
0166412-78-8	45705	1,2-cyclohexanedicarboxylic acid, diisononyl ester	

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
13463-67-7	93440	E171	Titanium dioxide	
001592-23-0	\	E470a	Calcium Stearate	

2. Experimental part

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 fatty food

Simulant	Olive oil (simulant "D2")
Test Condition	Overall Migration: 1h at 125°C + 10 days at 40°C Specific Migration: 1h at 125°C + 10days at 60°C



Cap Size (mm)	Jar volume (ml)	Global Migration	Specific Migration ESBO	Specific Migration PAD
48	156	8,5	<10	3
53	212	9,0	<10	2,2
63	212	12,0	<10	2,6
66	250	13,5	10	2,5
77	370	16,8	10,5	2,5
82	580	22,2	11,6	2,5
89	720	28,5	12,5	2,0
100	1000	35,0	14,0	2,0

Migration values are expressed in mg/cap

Data for no fatty food

Simulant	Acid Acetic 3% (simulant "B")
Test Condition	1h at 125°C + 10days at 40°C
Result (from cap size 48mm to 110mm)	< 4mg/cap

Simulant	Ethanol 20% (simulant "C")
Test Condition	1h at 125°C + 10days at 40°C
Result (from cap size 48mm to 110mm)	< 5mg/cap

Simulant	Water
Test Condition	1h at 125°C + 10days at 40°C
Result (from cap size 48mm to 110mm)	< 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 : 08/01/2018

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