

## STATEMENT OF CONFORMITY

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# <u>Subject: Tecnocap caps (range: from 33 mm to 110 mm) lined with compound mod R47 (TPR47BS)</u>

The caps in subject are suitable for:

- Condition of use: heat treatment of pasteriusation, up to 100°C for 1 h, and shelf life up to 36 months
- ➤ Food category: Products listed in Annex to 85/572/EC and specifically suggested for fatty foods or containing free oil.

#### 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
- All the materials used (metal, coatings, enamels and compound) correspond completely to the European directives 2002/72/EC, 2002/19/EC (and amendements)
- Tecnocap caps comply with directives 1935/2004/EC, 2023/2006/EC, 1895/2005/EC, 975/2009/EC.
- EU Regulation 372/2007, amended by 597/2008, remains still into the force for caps produces up to 30<sup>th</sup> April 2009.
- Tecnocap compounds are free from phthalates and adipates (us DEHA), 2-EHA- free and SEM-free (2004/1/EC).





#### 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 (Annex 1), which is integrant part of this Statement.

The following substances are used to manufactures the compound as in subject.

For used substances which are subject to a restriction and/or specifications in food for which purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC exist are listed as follows:

CAS	PM ref.	Název	Omezení/specifikace
9002-86-2	\	PVC resins	
000075-01-4	26050	Vinyl chloride monomer	1 mg/kg
08013-07-8	88640	Epoxidised Soya Bean Oil	60 mg/kg or 10 mg/dm <sup>2</sup>
1	76866	Polyadipates	30 mg/kg or 5 mg/dm <sup>2</sup>
736150-63-3	55910	Glycerides, monohydrogenated acetates	
00077-90-7	93760	Tributyl acetyl citrate	
000109-43-3	85360	Sebacic ester, dibutyl ester	7
030899-62-8	56800	Glicerol monolaurate diacetate	
1592-23-0	\	calcium stearate	
557-05-1	1	zinc stearate	
13463-67-7	93440	titanium dioxide	
63148-62-9	23547	silicone	
301-02-0	68960	oleamide	
112-84-5	52720	erucamide	

#### 2. - Experimental part

A total migration test has been carried out according to the guidelines laid down in Directive 82/711/EC with amendments (Directive 93/8/EEC and 97/48/EC) and Directive 85/572/EEC.



<sup>2.1 -</sup> Global and Specific migration



Simulant	Olive oil (simulant "D")		
Test Condition	1h at 100°C + 10 days at 40°C		

Cap size (mm)	Jar volume (ml)	Global migration.	Specific migration ESBO	Specific migration PAD	Specific migration AMG	Specific migration ATBC	Specific migration DBS		
53	212	9,0	2,1	0,6	1,3	1,1	1,1		
58	250	11,0	2,0	<1	3,1	1,0	3,3		
63	212	10,2	3,2	0,8	2,1	0,9	1,6		
70	330	16,0	3,3	1,2	<2	0,5	1,6		
77	IN PROGRESS AT DATE OF DOCUMENT								
82	580	19,7	< LQ	<lq< td=""><td><lq< td=""><td>0,9</td><td>1,9</td></lq<></td></lq<>	<lq< td=""><td>0,9</td><td>1,9</td></lq<>	0,9	1,9		

Values are expressed in mg/cap

### 2.2 - specific migration into the food

Specific migration values, obtained by experimental data of theoretical calculation for plasticizers used, are as follow:

Cap size (mm)	Storage condition.	Storage timing.	Specific migration ESBO	Specific migration PAD	Specific migration AMG	Specific migration ATBC	Specific migration DBS	Global migration as sum of SM
63	30°C	60 days	<10	nd	nd	<2	2,0	2,0
	30°C	100 days	<10	nd	nd	<2	3,5	3,5
	30°C	150 days	<10	nd	nd	<2	4,0	4,0
	30°C	150 days + additionally 10 days at 70°C	<10	nd	<20	3,1	7,9	11,0

Values are expressed in mg/kg

Data reported are referred to Green Pesto filled in 212 ml jar in industrial condition and preserved using 63 mm caps lined with mod. R47 (TPR47BS).

Note: 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. Test realized with simulants are in respect to 2002/72/EC; 82/72/EC and amending 85/572/EC.

Some parameters, like foodstuff ingredients, closing process, volume jar, heat treatment, storage condition of finished product, could influence migration that may result higher.

Fillers and packers have to 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.

Variability of parameters above reported is not under control of Tecnocap so we cannot be responsible for use condition and process/storage of caps.

Date: 27th April, 2010

Tecnocap s.r.o.

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