

	<b>FOOD CONTACT DECLARATION</b>	QA-MOD-027/01 Ref. QA-SOP-010 Valid from 12/02/2019
QA: C. Ferdenzi		

### GENERAL INFORMATION

MANUFACTURER BORMIOLI PHARMA - Legal Office: Corso Magenta, 84 - 20123 Milano (MI), Italy  
 PRODUCT TAMPER EVIDENT CAP  
 DATE OF DECLARATION 04/04/2019

### COMPONENTS OF THE ITEM

The aforementioned product is composed of:

1	EXTERNAL CAP
2	RING

### DECLARATION IN COMPLIANCE WITH EUROPEAN REGULATION

Regulation 1935/2004/CE  
 Regulation 1895/2005/CE  
 Regulation 10/2011/EU and its following amendments  
 Regulation 2023/2006/CE

### USA REGULATION

[PP PURELL HP570M](#) The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(1)(i) and (c)1.1a. This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

### ITALIAN REGULATION

DPR 777/82 and its following amendments  
 DM 21/03/1973 and its following amendments  
 DL 10/02/2017 , n. 29

### STATEMENT ON RAW MATERIALS

The plastic item covered by this declaration has been manufactured only with monomers, additives and other starting substances that are authorised under Regulation (EC) No. 10/2011.

The item is manufactured in Bormioli Pharma plants with the following raw materials:

1	EXTERNAL CAP: POLYPROPYLENE PURELL HP570M + BLACK COLORANT PP9AEF12020
2	RING: LOW DENSITY POLYETHYLENE PCG22 + SLIDING AGENT CESA SLIP MB2

### STATEMENT ON FINISHED PRODUCT

#### COMPLIANCE WITH OVERALL MIGRATION LIMIT

As per Regulation 10/2011/EU, to demonstrate compliance with the global migration limit for all types of food, the test is carried out in food simulants A, B and D2 at the following test conditions:

(A) Ethanol 10% (v/v) 60°C, 10dd  
 (B) Acetic Acid 3% (w/v) 60°C, 10dd  
 (D2) Vegetable oil 60°C, 10dd

The aforementioned testing conditions provide the following contact conformity:

*Contact with all types of food product;*

*Even more than 6 months;*

*At room temperature (or below), heated up to 70°C for 2 hours or up to 100°C for 15 minutes.*

The overall migration test has confirmed that the product covered by this declaration is in conformity with the overall migration limit of 10 mg / 1 dm<sup>2</sup>.

#### COMPLIANCE WITH SPECIFIC MIGRATION LIMIT

As per Regulation 10/2011/EU, to demonstrate compliance with the specific migration limit for all types of food, the test is carried out in food simulants A, B and D2 at the following test conditions:

(A) Ethanol 10% (v/v) 60°C, 10dd  
 (B) Acetic Acid 3% (w/v) 60°C, 10dd  
 (D2) Vegetable oil 60°C, 10dd

The aforementioned testing conditions provide the following contact conformity:

Contact with all types of food product;

Even more than 6 months;

At room temperature (or below), heated up to 70°C for 2 hours or up to 100°C for 15 minutes.

The material contains substances subject to restriction, according to the above mentioned regulation:

Raw material	Name of substance	CAS No.	Limit (mg/kg)
POLYPROPYLENE PURELL HP570M	9,9-bis(methoxymethyl)-9H-fluorene	0182121-12-6	0,05
BLACK PP9AEF12020	1,3,5- Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)tione*	0027676-62-6	5
CESA-slip MB2	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	0002082-79-3	6

The specific migration test has confirmed that the product covered by this declaration is in conformity with the specific migration limits associated with each substance reported in the chart.

The overall migration limits, together with the other specific restrictions of the monomers and/ or additives present in the material, are respected at the using condition described above. The statement is supported by analytical tests carried out in compliance with the European Regulation No 10/2011 (and its following amendments) or based on calculations made considering the content of the substances subject to migration limits.

The calculations are made with the assumption that 1 kg of food is in contact with 6 dm<sup>2</sup> of packaging material.

#### INFORMATION ABOUT "DUAL-USE" ADDITIVES IN THE PRODUCT

In the material there aren't substances regulated by the Regulations 1333/08/CE and 1334/08/CE (substances are also called additive "dual use").

According to experimental data and / or theoretical calculations provided by raw materials supplier.

In the material there are substances regulated by the Regulations 1333/08/CE and 1334/08/CE (substances are also called additive "dual use"). According to experimental data and / or theoretical calculations provided by raw materials supplier, these substances are in accordance with the provisions of Regulation 10/2011/UE, Art. 11, comma 3:

Raw material	Name of substance	ID No.
POLYPROPYLENE PURELL HP570M	Calcium salts of fatty acids	E470a
BLACK PP9AEF12020	Stearic acid & derivates	106
CESA-slip MB2	Talc	615

#### COMPLIANCE WITH SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINES in aqueous food simulants

To guarantee the compliance to Reg. (CE) 1935/2004 and Reg. (EU) 10/2011, plastic materials and articles shall not release primary aromatic amines, except for those listed in Table 1 of Annex I, in quantities detectable in foodstuff or food simulants. The limit of detection is 0.01 mg of substance per kg of food product or food simulant. The limit of detection is applied to the sum of the primary aromatic amines released.

The product was tested with following simulant at following conditions:

(B) Acetic Acid 3% (w/v) 60°C, 10dd

The specific migration test has confirmed that the product covered by this declaration is in conformity with the specific migration limits associated with primary aromatic amines.

#### COMPLIANCE WITH SPECIFIC MIGRATION OF METALS in aqueous food simulants

To guarantee the compliance to Reg. (EU) 10/2011, plastic materials and articles shall not release the mentioned metals beyond the limits expressed in Reg. (EU) 10/2011.

This declaration is issued basing on the latest updated of the metals' list (and their associated migration limit) in Reg. (EU) 10/2011.

The product was tested with following simulant at following conditions:

(B) Acetic Acid 3% (w/v) 60°C, 10dd

The specific migration test has confirmed that the product covered by this declaration is in conformity with the specific migration limits associated with metals listed in Reg. (EU) 10/2011.

Angela Breveglieri  
 Group Quality Manager



