



FOOD CONTACT DECLARATION

Mod.PP109-
Mar 19

GENERAL INFORMATION

MANUFACTURER PUNTO PACK S.p.A. SOCIETA' BENEFIT
Legal Office: via F. Borromini, 42 – 50028 Barberino Tavarnelle (FI)
PRODUCT WHITE HDPE PILL JAR
DATE OF DECLARATION 16/02/2026

COMPONENT OF THE ITEM

The aforementioned product is composed of: HDPE (Environmental Code: HDPE 2)

DECLARATION IN COMPLIANCE WITH

EUROPEAN REGULATION

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

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 authorized under Regulation (EU) n. 10/2011.

The item is manufactured in Parma plant with the following raw materials:

1. Food grade HDPE Marlex 5502;
2. Masterbatch MB PE WHITE 28584.

STATEMENT ON FINISHED PRODUCT

COMPLIANCE WITH OVERALL MIGRATION LIMIT

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

- | | | |
|------|----------------------|------------|
| (A) | Ethanol 10% (v/v) | 40°C, 10dd |
| (B) | Acetic Acid 3% (v/v) | 40°C, 10dd |
| (D2) | Vegetable Oil | 40°C, 10dd |

The aforementioned testing conditions provide the following contact conformity:

- Contact with all types of food product covered by the mentioned above simulants;
- Any long-term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 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 dm²

COMPLIANCE WITH SPECIFIC MIGRATION LIMIT

As per regulation 10/2011/EU to demonstrate compliance with the specific migration limit, 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% (v/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 covered by the mentioned above simulants;
- Contact times above 30 days at room temperature and below.

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

Raw material	Name of substance	CAS N.	FCM	Limit (mg/kg)
HDPE Marlex 5502 White 28584	1,4-butanediol	0000110-63-4	254	5
	Tetrahydrofuran	0000109-99-9	246	0,6
	Ethyleneglycol	0000107-21-1	227	30
	Terephthalic acid	0000100-21-0	785	7,5
	Zinc salts	0091051-01-3	-	5

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



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material, are respected at the using condition described above. The statement is supported by analytical tests carried out in compliance with the European Regulation N. 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 dm² 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 (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 (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 17/2011/UE, Art.11, comma 3:

Raw material	Name of substance	CAS N.
White 28584	Titanium dioxide	0013463-67-7

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

To guarantee the compliance to Reg. (CE) 1935/2004 and Reg (UE) 10/2011, plastic materials and articles shall not release primary aromatic amines, except for those listed in Table I oh 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 the following conditions:

(B) Acetic Acid 3% (v/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 (UE) 10/2011, plastic materials and articles shall not release the mentioned metals beyond the limits expressed in Reg. (UE) 10/2011. This declaration is issued basing on the latest updated of the metals' list (and their associated migration limit) in Reg (UE) 10/2011.

The product was tested with following simulant at the 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 (UE) 10/2011.

COMPLIANCE WITH COLOR MIGRATION in aqueous food simulants

As per DM 21/03/73 to demonstrate compliance with the migration of colors in all types of food, the test is carried out in food simulants:

- (A) Ethanol 10% (v/v)
- (B) Acetic Acid 3% (w/v)
- (D2) Vegetable Oil

At the following test conditions: 40°C, 10dd

The test has confirmed that the product covered by this declaration is in conformity with the migration associated with color as per DM 21/03/73.

Andrea Dallargine
Quality Manager and Regulatory Affairs
Punto Pack S.p.A. Società Benefit