



DECLARATION OF CONFORMITY

Manufacturer: SANTEX 2000 Internacional SL; Paseo de la castellana 141, plantas 18 y 19, Cuzco IV 28046-MADRID (SPAIN)

Declares that the product:

POLYETHYLENE GOWN

One size

Product code: DC01WC

- Complies with the applicable legislation on materials intended to come into contact with food in accordance with Regulation (EC) No 1935/2004, as amended, and all implementing legislation.
- The substances used are included in the Positive Lists for plastic materials and articles intended to come into contact with food, in accordance with Regulation (EU) No 10/2011, Regulation (EU) 2020/1245, and all implementing legislation.
- The products have been subjected to the relevant migration tests in accordance with the requirements set out in Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended.
- The products comply with Commission Regulation (EC) No 2023/2006 on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food.
- Overall migration testing has been carried out using a surface area-to-food volume ratio of 6 dm² per kg of food, in accordance with the applicable regulatory requirements.

Overall Migration Testing

Food simulants	Test Conditions		
	Duration	Temperature	Overall Migration (mg/dm ²) (limit < 10)
3% Acetic Acid	2 h	70 °C	Pass
10% Ethanol	2 h	70 °C	Pass
20% Ethanol	2 h	70 °C	Pass
50% Ethanol	2 h	70 °C	Pass
95% Ethanol	2 h	60 °C	Pass
Olive Oil	0,5 h	40 °C	Pass

Date: 06/07/2026

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Specific Migration of Heavy Metals
Test conditions: 70°C, 2 hours, 3% aqueous acetic acid solution

Metal	Maximum Permitted Limit (mg/kg)	Result (mg/kg)
Arsenic (As)	0,01	N.D.
Aluminum (Al)	1	N.D.
Barium (Ba)	1	N.D.
Cobalt (Co)	0,05	N.D.
Copper (Cu)	5	N.D.
Cadmium (Cd)	0,002	N.D.
Chromium (Cr)	0,01	N.D.
Lithium (Li)	0,6	N.D.
Zinc (Zn)	5	N.D.
Manganese (Mn)	0,6	N.D.
Mercury (Hg)	0,01	N.D.
Lead (Pb)	0,01	N.D.
Iron (Fe)	48	N.D.
Nickel (Ni)	0,02	N.D.
Antimony (Sb)	0,01	N.D.
Europium (Eu) + Gadolinium (Gd) + Lanthanum (La) + Terbium (Tb)	0,05	N.D.

N.D. = Not Detected; below the Maximum Permitted Limit.

Applications

This product is intended for contact with all types of fatty, aqueous, and acidic foods, except foods intended for infants and young children. It is commonly used for the manual handling of food, including food products containing animal fat.

Conditions of Use

The material should be stored in a cool, dry place, protected from significant variations in temperature and relative humidity. Direct exposure to sunlight may cause changes in the product's characteristics and colour.

Other Information

This declaration applies only to the products in their original form, as supplied by SANTEX 2000 INTERNACIONAL, S.L., and does not cover any subsequent modifications made to the product.

Signed on behalf of SANTEX 2000 Internacional SL:

Quality and Regulatory Affairs Manager

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