PH-STA-147 Document Reference:

Document Issue Number:

Document Issue Date:

Page 1 of 4

01

15/11/2023



## **Pura Nitrile Food contact statement**

Product Brand: Polyco	
Product Description: Pura Nitrile Flocklined Gloves	
Product Code:	17N (Red), 27N (Yellow), 37N (Green), 47N (Blue)

Polyco Healthline Ltd hereby declares that the above-mentioned products are in compliance with the rules of:

Regulation (EC) 1935/2004 (as amended) of the European Parliament and of the Council on materials and articles intended to come into contact with food.

### and were manufactured in accordance with:

- The requirements of Commission Regulation (EC) No. 2023/2006 relating to manufacturing practice for materials and articles intended to come into contact with food.

#### and meet the demands of:

Commission Regulation (EU) No 10/2011 of the Commission of January 2011 on materials and articles made of plastic which are intended to come into contact with food (as amended); union list of authorised monomers.

### and were examined in accordance with:

 Commission Regulation (EU) No 10/2011 Annex III and Annex V for selection of condition and EN 1186 parts 1 and 9, for test methods (materials and articles in contact with foodstuffs - plastics).

### Test results:

### Overall migration test:

Simulant used	Test condition	Limit mg/dm <sup>2</sup>	Result mg/dm²
3% Acetic acid	40°C / 2.0 hours	10	<1.0
10% Ethanol	40°C / 2.0 hours	10	<1.0
20% Ethanol	40°C / 2.0 hours	10	<1.0
50% Ethanol	40°C / 2.0 hours	10	<1.0

Document Reference: PH-STA-147 Document Issue Number:

Document Issue Date:

Page 2 of 4

01 15/11/2023



## Specific migration test:

Test item	Limit mg/kg	Result mg/kg
Aluminium	1.0	<0.05
Ammonium	8	<1.0
Antimony	0.04	<0.04
Arsenic	ND	<0.01
Barium	1	<0.05
Cadmium	ND	<0.002
Calcium	*	<0.05
Chromium	ND	<0.01
Cobalt	0.05	<0.05
Copper	5	<0.05
Iron	48	<0.05
Lead	ND	<0.01
Lithium	0.6	<0.05
Magnesium	*	<0.05
Manganese	0.6	<0.05
Mercury	ND	<0.01
Nickel	0.02	<0.02
Potassium	*	0.05
Sodium	*	<0.05
Zinc	5	0.10

\*In accordance with Commission Regulation (EU) No. 10/2011 Annex V Chapter 2 the specific migration in the section test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test. Compliance of the material or article shall then be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test.

Note: For repeat use only.

This declaration is supported by Test Report: CHM0267804/1808/CL/D/Interim & CHM0330797/2219/JH.

Document Reference: PH-STA-147
Document Issue Number: 01

Document Issue Date: 15/11/2023

Page 3 of 4

Polyco Healthline

Tel: +44 (0)33 3320 8550

# **Suitable Food Types**

	<u> </u>	
	Clear beverages: non-alcoholic, or alcoholic with ≤6% alcohol content	Suitable
Beverages	Cloudy beverages: non-alcoholic, or alcoholic with ≤6% alcohol content	Suitable
	Alcoholic beverages with 6 - 20% alcohol content	Suitable
	Alcoholic beverages with >20% alcohol content and all cream liqueurs	Suitable
	Miscellaneous: undenatured ethyl alcohol	Not Suitable
	Starches, cereals, flour, meal, dry pasta and similar products, fresh pasta	Suitable
Bread, cereals, pastries, cakes, etc.	Bread, pastry, biscuits, cakes, and similar products: dry or fresh; with fats or oils on the surface	Not Suitable
	Bread, pastry, biscuits, cakes, and similar products: dry or fresh; without fats or oils on the surface	Suitable
	Character shouldte spated products and shouldte substitutes	Not Suitable
	Chocolate, chocolate-coated products, and chocolate substitutes  Confectionery products in solid or paste form, with fatty substances on the	Not Suitable
	surface	Not Suitable
Chocolate, sugar, and confectionery	Confectionery products in solid form, without fatty substances on the surface	Suitable
products	Confectionery products in moist form, without fatty substances on the surface	Suitable
	Sugar and sugar products in solid form; crystalline or powdered	Suitable
	Molasses, sugar syrups, honey	Suitable
	I	
	Fruit and vegetables, unpeeled and uncut	Suitable
	Fruit and vegetables, peeled and/or cut	Suitable
	Processed fruit and vegetables, dried or dehydrated	Suitable
Fruits and	Processed fruit and vegetables in purée form	Suitable
vegetables	Preserved fruit, in an oily medium	Not Suitable
3	Preserved vegetables, in an oily medium	Not Suitable
	Preserved fruit and vegetables, in an alcoholic medium	Suitable
	Nuts: shelled and roasted, or shelled and dried, flaked, or powdered	Suitable
	Nuts: paste or cream form	Not Suitable
Fats and oils	Animal and vegetable fats and oils, natural or treated (cocoa butter, lard, olive oil, etc.)	Not Suitable
	Margarine, butter, and other fats and oils made from water emulsions in oil	Not Suitable
	Fish: fresh, chilled, processed, smoked or salted, including fish eggs	Suitable if no fatty contact
	Fish, crustaceans, and molluscs: preserved in an oily medium	Suitable
	Fish, crustaceans, and molluscs: preserved in an aqueous medium	Suitable
	Crustaceans and molluscs: fresh within the shell	Suitable
Animal products (meat, seafood, eggs, etc.)	Meat and processed meat products: fresh, chilled, salted, or smoked	Suitable if no fatty contact
	Marinated meat: in an oily medium	Not Suitable
	Preserved meat: in a fatty or oily medium	Not Suitable
	Preserved meat: in an aqueous medium	Suitable
	Whole eggs, egg yolk, or egg white: powdered, dried, or frozen	Suitable
	Egg yolk or egg white: liquid or cooked	Suitable

Document Reference: PH-STA-147
Document Issue Number: 01

Document Issue Date: 15/11/2023

Page 4 of 4



Tel: +44 (0)33 3320 8550

	Whole, skimmed, or partly dried milk	Suitable
Dairy products	Milk powder, including infant formula	Suitable
	Cream, sour cream, and fermented milk (yoghurt, buttermilk, etc.)	Suitable
	Cheese: whole, with inedible rind	Suitable if no fatty contact
	Cheese: without rind or with edible rind	Suitable
	Cheese: processed and soft cheeses	Suitable
	Preserved cheese: in an oily medium	Not Suitable
	Preserved cheese: in an aqueous medium	Suitable
	Sauces: with aqueous character	Suitable
Miscellaneous -	Sauces: with fatty character (e.g., mayonnaise, salad creams)	Not Suitable
condiments and sauces	Mustard	Suitable if no fatty contact
Sauces	Vinegar	Suitable
	Sandwiches, toasted bread, pizza: with fatty topping/fillings	Not Suitable
	Sandwiches, toasted bread, pizza: without fatty toppings/fillings	Suitable
	Soups, sauces, broths: powdered or dried with fatty characters	Not Suitable
Miscellaneous -	Soups, sauces, broths: powdered or dried without fatty characters	Suitable
mixed foods	Soups, sauces, broths: in any other form with fatty characters	Not Suitable
	Soups, sauces, broths: in any other form without fatty characters	Suitable
	Fried or roasted foods of vegetable origin (fried potatoes, fritters)	Not Suitable
	Fried or roasted foods of animal origin	Not Suitable
	Dried foods: with fatty substances on the surface	Not Suitable
	Dried foods: without fatty substances on the surface	Suitable
	Herbs and spices	Suitable
	Spices and seasoning in an oily medium (e.g., pesto, curry paste)	Not Suitable
Miscellaneous -	Coffee and coffee substitutes: granulated or powdered	Suitable
others	Cocoa powder	Suitable
	Cocoa paste	Not Suitable
	Concentrated extracts with ≥6% alcohol content	Suitable
	Frozen or deep-frozen foods	Suitable
	Ice-creams	Suitable