Document Reference: PH-STA-130 Document Issue Number: 02

08/11/2023

Document Issue Date:

Page 1 of 3



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ND45 Food contact statement

Product Brand:	duct Brand: Polyco Healthline	
Product Description:	Synthetic Nitrile Rubber Glove (N-Dura)	
Product Code:	ND45	

Polyco Healthline Ltd hereby confirms that the above-mentioned product was were submitted under the OEM brand for overall migration analysis in accordance with Regulation (EU) 10/2011 and EN 1186 series of standards.

- BS EN 1186 part 9:2002 (Modified) materials and articles in contact with foodstuffs plastics test methods for overall migration into aqueous food simulants by article filling (modified) for 10 minutes at 40°C.
 - » 10% Ethanol (Simulant A in Commission Regulation No. 10/2011)
 - » 3% Acetic Acid (Simulant B in Commission Regulation No. 10/2011)
 - » Distilled water (Simulant A in EN1186-1:2002)
- TES-AC-500: Based on EN1186 Part 6:2022, Materials and articles in contact with foodstuffs - plastics test methods for overall migration into olive oil by pouch method for 10 minutes at 40°C.
 - » Vegetable Oil (Simulant D2 in Commission Regulation No. 10/2011)

Note – Sunflower oil was used as an alternative to rectified olive oil – "reference simulant D". The sunflower oil used has characteristics in accordance with those specified in Annex A of BS EN 1186-1:2002.

Test results:

Overall migration test:

Simulant used	Test condition	Limit mg/dm ²	Result mg/dm²
10% Ethanol	40°C / 10 Minutes	10	<1.0
3% Acetic Acid	40°C / 10 Minutes	10	<1.0
Distilled Water	40°C / 10 Minutes	10	<1.0
Sunflower Oil	40°C / 10 Minutes	10	<1.0

Note: Testing was carried out assuming repeat use articles, three tests were carried out for each test specimen and only the third result is reported.

This statement is supported by Test Report: CHM0241040/1550/EN/FINAL, Issued by SATRA Technology Centre Ltd.

Document Reference: PH-STA-130 Document Issue Number: 02

Document Issue Date: 08/11/2023

Page 2 of 3



Suitable Food Types

	Clear beverages: non-alcoholic, or alcoholic with ≤6% alcohol content	Suitable			
	Cloudy beverages: non-alcoholic, or alcoholic with ≤6% alcohol content	Suitable			
Beverages	Alcoholic beverages with 6 - 20% alcohol content	Suitable			
1	Alcoholic beverages with >20% alcohol content and all cream liqueurs	Suitable			
1	Miscellaneous: undenatured ethyl alcohol	Not Suitable			
	Starches, cereals, flour, meal, dry pasta and similar products, fresh pasta	Suitable			
	Bread, pastry, biscuits, cakes, and similar products: dry or fresh; with fats or bils on the surface	Not Suitable			
	Bread, pastry, biscuits, cakes, and similar products: dry or fresh; without fats or oils on the surface	Suitable			
		Not Cuitable			
	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			
-	Confectionery products in moist form, without fatty substances on the surface	Suitable			
	Sugar and sugar products in solid form; crystalline or powdered	Suitable			
1	Molasses, sugar syrups, honey	Suitable			
	- 1				
	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			
_ <u>_ F</u>	Preserved vegetables, in an oily medium	Not Suitable			
F	Preserved fruit and vegetables, in an alcoholic medium	Suitable			
1	Nuts: shelled and roasted, or shelled and dried, flaked, or powdered	Suitable			
1	Nuts: paste or cream form	Not Suitable			
	Animal and vegetable fats and oils, natural or treated (cocoa butter, lard, blive oil, etc.)	Not Suitable			
	Margarine, butter, and other fats and oils made from water emulsions in oil	Not Suitable			
F	Fish: fresh, chilled, processed, smoked or salted, including fish eggs	Suitable if no fatty contact			
l l	Fish, crustaceans, and molluscs: preserved in an oily medium	Not 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			
F	Preserved meat: in a fatty or oily medium	Not Suitable			
F	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-130 Document Issue Number: 02

Document Issue Date: 08/11/2023

Page 3 of 3



Dairy products	Whole, skimmed, or partly dried milk	Suitable
	Milk powder, including infant formula	Suitable
	Cream, sour cream, and fermented milk (yoghurt, buttermilk, etc.)	Suitable
	Cheese: whole, with inedible rind	Suitable
	Cheese: without rind or with edible rind	Suitable if no fatty contact
	Cheese: processed and soft cheeses	Suitable
	Preserved cheese: in an oily medium	Not Suitable
	Preserved cheese: in an aqueous medium	Suitable
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Miscellaneous - condiments and sauces	Sauces: with aqueous character	Suitable
	Sauces: with fatty character (e.g., mayonnaise, salad creams)	Not Suitable
	Mustard	Suitable if no fatty contact
	Vinegar	Suitable
	Sandwiches, toasted bread, pizza: with fatty topping/fillings	Not Suitable
	Sandwiches, toasted bread, pizza: with latty 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