



EC DECLARATION OF CONFORMITY

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

Declares that the product:

POWDER-FREE NITRILE EXAMINATION GLOVES

Sizes: XS / S / M / L / XL

Product code: GD19, GD20, GD21, GD22, GD23, GD30
(Please check the Anex I for more details)

The product covered by this declaration complies with Commission Regulation (EU) No. 10/2011, as amended, on plastic materials and articles intended to come into contact with food. In addition, it meets Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food, as well as Regulation (EC) 2023/2006 on good manufacturing practices for materials and articles intended to come into contact with food.

Under normal conditions of use, these materials do not transfer substances to food in quantities that could be harmful to health, nor do they unacceptably alter the composition, taste, odor, or appearance of the food.

Compliance was determined using the contact surface-to-volume ratio of $6dm^2/L$.

The material has been subjected to the corresponding migration tests, which are shown in the test report PTC23042503602C-EN01 and are presented below

1. OVERALL MIGRATION

Method: According to EN 1186-1:2002, EN 1186-2:2002, EN 1186-3:2002

Test conditions: 40°C for 30 minutes

Simulant Used(s)	Unit	Limit(s)	RL	Result(s)	Conclusion(s)
				1	
10% Ethanol	mg/dm ²	10	3	N.D.	PASS
3% Acetic acid	mg/dm ²	10	3	3.8	PASS
Olive oil	mg/dm ²	10	3	N.D.	PASS

Date: 11/02/2026

2. SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINE

2.1 Test conditions: 40°C for 30 minutes in 10% Ethanol and 3% Acetic Acid

Method: According to EN 13130-1:2004, analysis by HPLC-MS-MS

No.	Test Item(s)	RL (mg/kg)	Limit (mg/kg)	Result (mg/kg)	
				1	
				10% Ethanol	3% Acetic acid
(1)	o-Toluidine	0.002	N.D.	N.D.	N.D.
(2)	2-Methoxyaniline	0.002	N.D.	N.D.	N.D.
(3)	p-Chloroaniline	0.002	N.D.	N.D.	N.D.
(4)	p-Kresidine	0.002	N.D.	N.D.	N.D.
(5)	2,4,5-Trimethylaniline	0.002	N.D.	N.D.	N.D.
(6)	4-Chloro-o-Toluidine	0.002	N.D.	N.D.	N.D.
(7)	2,4-Toluylenediamine	0.002	N.D.	N.D.	N.D.
(8)	2,4-Diaminoanisole	0.002	N.D.	N.D.	N.D.
(9)	2-Naphthylamine	0.002	N.D.	N.D.	N.D.
(10)	2-Amino-4-nitrotoluene	0.002	N.D.	N.D.	N.D.
(11)	4-Aminodiphenyl	0.002	N.D.	N.D.	N.D.
(12)	p-Aminoazobenzene	0.002	N.D.	N.D.	N.D.
(13)	4,4'-Oxydianiline	0.002	N.D.	N.D.	N.D.
(14)	Benzidine	0.002	N.D.	N.D.	N.D.
(15)	4,4'-Diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(16)	o-Aminoazotoluene	0.002	N.D.	N.D.	N.D.
(17)	3,3'-Dimethyl-4,4'-diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(18)	3,3'-Dimethylbenzidine	0.002	N.D.	N.D.	N.D.
(19)	4,4'-Thiodianiline	0.002	N.D.	N.D.	N.D.
(20)	3,3'-Dichlorobenzidine	0.002	N.D.	N.D.	N.D.
(21)	4,4'-Methylene-bis-(2-chloraniline)	0.002	N.D.	N.D.	N.D.
(22)	3,3'-Dimethoxybenzidine	0.002	N.D.	N.D.	N.D.
(23)	1,3-Phenylendiamine	0.002	N.D.	N.D.	N.D.
(24)	Other Primary Aromatic Amine	0.01	Sum≤0.01	N.D.	N.D.
Conclusion				PASS	PASS

2.2 Test conditions: 40°C for 30 minutes in 95% Ethanol and Isooctane

Method: According to EN 13130-1:2004, analysis by HPLC-MS-MS

No.	Test Item(s)	RL (mg/kg)	Limit (mg/kg)	Result (mg/kg)	
				1	
				95%Ethanol	Isooctane
(1)	o-Toluidine	0.002	N.D.	N.D.	N.D.
(2)	2-Methoxyaniline	0.002	N.D.	N.D.	N.D.
(3)	p-Chloroaniline	0.002	N.D.	N.D.	N.D.
(4)	p-Kresidine	0.002	N.D.	N.D.	N.D.
(5)	2,4,5-Trimethylaniline	0.002	N.D.	N.D.	N.D.
(6)	4-Chloro-o-Toluidine	0.002	N.D.	N.D.	N.D.
(7)	2,4-Toluylenediamine	0.002	N.D.	N.D.	N.D.
(8)	2,4-Diaminoanisole	0.002	N.D.	N.D.	N.D.
(9)	2-Naphthylamine	0.002	N.D.	N.D.	N.D.
(10)	2-Amino-4-nitrotoluene	0.002	N.D.	N.D.	N.D.
(11)	4-Aminodiphenyl	0.002	N.D.	N.D.	N.D.
(12)	p-Aminoazobenzene	0.002	N.D.	N.D.	N.D.
(13)	4,4'-Oxydianiline	0.002	N.D.	N.D.	N.D.
(14)	Benzidine	0.002	N.D.	N.D.	N.D.
(15)	4,4'-Diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(16)	o-Aminoazotoluene	0.002	N.D.	N.D.	N.D.
(17)	3,3'-Dimethyl-4,4'-diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(18)	3,3'-Dimethylbenzidine	0.002	N.D.	N.D.	N.D.
(19)	4,4'-Thiodianiline	0.002	N.D.	N.D.	N.D.
(20)	3,3'-Dichlorobenzidine	0.002	N.D.	N.D.	N.D.
(21)	4,4'-Methylene-bis-(2-chloraniline)	0.002	N.D.	N.D.	N.D.
(22)	3,3'-Dimethoxybenzidine	0.002	N.D.	N.D.	N.D.
(23)	1,3-Phenylendiamine	0.002	N.D.	N.D.	N.D.
(24)	Other Primary Aromatic Amine	0.01	Sum≤0.01	N.D.	N.D.
Conclusion				PASS	PASS

2.3 Test conditions: 40°C for 30 minutes in Olive Oil

Method: According to EN 13130-1:2004, analysis by HPLC-MS-MS

No.	Test Item(s)	RL (mg/kg)	Limit (mg/kg)	Result (mg/kg)
				1
(1)	o-Toluidine	0.002	N.D.	N.D.
(2)	2-Methoxyaniline	0.002	N.D.	N.D.
(3)	p-Chloroaniline	0.002	N.D.	N.D.
(4)	p-Kresidine	0.002	N.D.	N.D.
(5)	2,4,5-Trimethylaniline	0.002	N.D.	N.D.
(6)	4-Chloro-o-Toluidine	0.002	N.D.	N.D.
(7)	2,4-Toluylenediamine	0.002	N.D.	N.D.
(8)	2,4-Diaminoanisole	0.002	N.D.	N.D.
(9)	2-Naphthylamine	0.002	N.D.	N.D.
(10)	2-Amino-4-nitrotoluene	0.002	N.D.	N.D.
(11)	4-Aminodiphenyl	0.002	N.D.	N.D.
(12)	p-Aminoazobenzene	0.002	N.D.	N.D.
(13)	4,4'-Oxydianiline	0.002	N.D.	N.D.
(14)	Benzidine	0.002	N.D.	N.D.
(15)	4,4'-Diaminodiphenylmethane	0.002	N.D.	N.D.
(16)	o-Aminoazotoluene	0.002	N.D.	N.D.
(17)	3,3'-Dimethyl-4,4'-diaminodiphenylmethane	0.002	N.D.	N.D.
(18)	3,3'-Dimethylbenzidine	0.002	N.D.	N.D.
(19)	4,4'-Thiodianiline	0.002	N.D.	N.D.
(20)	3,3'-Dichlorobenzidine	0.002	N.D.	N.D.
(21)	4,4'-Methylene-bis-(2-chloraniline)	0.002	N.D.	N.D.
(22)	3,3'-Dimethoxybenzidine	0.002	N.D.	N.D.
(23)	1,3-Phenyldiamine	0.002	N.D.	N.D.
(24)	Other Primary Aromatic Amine	0.01	Sum≤0.01	N.D.
Conclusion				PASS

3. SPECIFIC MIGRATION OF HEAVY METALS

3.1 Test conditions: 40°C for 2 hours in 3% Acetic Acid

Method: According to EN 13130-1:2004, analysis by ICP-OES and UV-vis

Test Item(s)	Unit	Limit(s)	RL	Result(s)
				1
Barium(Ba)	mg/kg	1	0.01	N.D.
Cobalt(Co)	mg/kg	0.05	0.01	N.D.
Copper(Cu)	mg/kg	5	0.01	N.D.
Iron(Fe)	mg/kg	48	0.01	0.04
Lithium(Li)	mg/kg	0.6	0.01	N.D.
Manganese(Mn)	mg/kg	0.6	0.01	N.D.
Zinc(Zn)	mg/kg	5	0.01	3.47
Aluminum (Al)	mg/kg	1	0.01	0.07
Nickel (Ni)	mg/kg	0.02	0.01	N.D.
Antimony(Sb)	mg/kg	0.04	0.01	0.02
Arsenic(As)	mg/kg	N.D.	0.01	N.D.
Cadmium(Cd)	mg/kg	N.D.	0.002	N.D.
Chromium(Cr)	mg/kg	N.D.*	0.01	N.D.
Europium(Eu)	mg/kg	SUM:0.05	0.01	N.D.
Gadolinium(Gd)	mg/kg		0.01	N.D.
Lanthanum(La)	mg/kg		0.01	N.D.
Terbium(Tb)	mg/kg		0.01	N.D.
Lead(Pb)	mg/kg	N.D.	0.01	N.D.
Mercury(Hg)	mg/kg	N.D.	0.01	N.D.
Magnesium(Mg)	mg/kg	--	0.01	2.86
Potassium(K)	mg/kg	--	0.01	0.41
Sodium(Na)	mg/kg	--	0.01	1.69
Calcium(Ca)	mg/kg	--	0.01	N.D.
Conclusion				PASS

3.2 Test conditions: 40°C for 2 hours in Olive Oil

Method: According to EN 13130-1:2004, analysis by ICP-OES and UV-vis

Test Item(s)	Unit	Limit(s)	RL	Result(s)
				1
Barium(Ba)	mg/kg	1	0.01	N.D.
Cobalt(Co)	mg/kg	0.05	0.01	N.D.
Copper(Cu)	mg/kg	5	0.01	N.D.
Iron(Fe)	mg/kg	48	0.01	N.D.
Lithium(Li)	mg/kg	0.6	0.01	N.D.
Manganese(Mn)	mg/kg	0.6	0.01	N.D.
Zinc(Zn)	mg/kg	5	0.01	N.D.
Aluminum (Al)	mg/kg	1	0.01	N.D.
Nickel (Ni)	mg/kg	0.02	0.01	N.D.
Antimony(Sb)	mg/kg	0.04	0.01	N.D.
Arsenic(As)	mg/kg	N.D.	0.01	N.D.
Cadmium(Cd)	mg/kg	N.D.	0.002	N.D.
Chromium(Cr)	mg/kg	N.D.*	0.01	N.D.
Europium(Eu)	mg/kg	SUM:0.05	0.01	N.D.
Gadolinium(Gd)	mg/kg		0.01	N.D.
Lanthanum(La)	mg/kg		0.01	N.D.
Terbium(Tb)	mg/kg		0.01	N.D.
Lead(Pb)	mg/kg	N.D.	0.01	N.D.
Mercury(Hg)	mg/kg	N.D.	0.01	N.D.
Magnesium(Mg)	mg/kg	--	0.01	N.D.
Potassium(K)	mg/kg	--	0.01	N.D.
Sodium(Na)	mg/kg	--	0.01	N.D.
Calcium(Ca)	mg/kg	--	0.01	N.D.
Conclusion				PASS



4. SPECIFIC MIGRATION OF NITROSAMINE AND NITROSATABLES SUBSTANCES

4.1 Test conditions: 40°C for 30 minutes in 3% Acetic Acid

Method: According to EN 12868:2017, analysis by GC-MS

Test Item(s)	Unit	Limit(s)	RL	Result(s)	Conclusion(s)
				1	
Specific migration of Nitrosamines	mg/kg	0.01	0.01	N.D.	PASS
Specific migration of Nitrosatable substances	mg/kg	0.1	0.1	N.D.	PASS

4.2 Test conditions: 40°C for 2 hours in Olive Oil

Method: According to EN 12868:2017, analysis by GC-MS

Test Item(s)	Unit	Limit(s)	RL	Result(s)	Conclusion(s)
				1	
Specific migration of Nitrosamines	mg/kg	0.01	0.01	N.D.	PASS
Specific migration of Nitrosatable substances	mg/kg	0.1	0.1	N.D.	PASS

The compliance of the materials has been evaluated by considering the predictably most critical usage scenarios, through the analysis of both surfaces of the material.

The transfer to the food product will not result in specific migrations exceeding the limits authorized in accordance with Regulation (EC) 10/2011 and its amendments.

It complies with Regulation (EC) 1895/2005, since BADGE, NOGE, or BFDGE are not used in the manufacture of this product.

Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with food is not applicable, as no type of recycled material is used in its production.

All current sanitary regulations are followed during processing and production, and the company is registered in the General Sanitary Food Registry under number 39.006069/M.

Date: 11/02/2026



The types of foods that may come into contact with the gloves covered by this declaration include all aqueous, acidic, or fatty foods, provided that the contact occurs at a temperature below 40 °C and for a maximum duration of 30 minutes. However, it is recommended to minimize the contact time with acidic foods or to avoid such contact entirely.

The material must be stored in a cool, dry place, without significant fluctuations in temperature or relative humidity. Direct exposure to sunlight may cause changes in the product's properties and color.

Signed in Madrid on behalf of SANTEX 2000 Internacional SL:

A handwritten signature in blue ink, appearing to read "Stefan Vintu", written over a faint, light blue rectangular stamp.

Stefan Vintu
Quality and RA Manager

Date: 11/02/2026



ANEX I

COLOR	SIZES				
	XS	S	M	L	XL
BLUE	GD19BA	GD19BB	GD19BC	GD19BD	GD19BE
	GD20BA	GD20BB	GD20BC	GD20BD	GD20BE
		GD21BB	GD21BC	GD21BD	GD21BE
		GD22BB	GD22BC	GD22BD	GD22BE
		GD30BB	GD30BC	GD30BD	GD30BE
BLACK	GD19NA	GD19NB	GD19NC	GD19ND	GD19NE
	GD20NA	GD20NB	GD20NC	GD20ND	GD20NE
		GD21NB	GD21NC	GD21ND	GD21NE
		GD23BB	GD23BC	GD23BD	GD23BE
WHITE	GD20WA	GD20WB	GD20WC	GD20WD	GD20WE
MAGENTA	GD20MA	GD20MB	GD20MC	GD20MD	GD20ME
PINK	GD20RA	GD20RB	GD20RC	GD20RD	GD20RE
PURPLE	GD20PA	GD20PB	GD20PC	GD20PD	GD20PE
COBALT BLUE	GD20CA	GD20CB	GD20CC	GD20CD	GD20CE
GREEN	GD20GA	GD20GB	GD20GC	GD20GD	GD20GE