



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 VINYL EXAMINATION GLOVES

Sizes: S / M / L / XL

Product code: GD10, GD14

(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.

To determine compliance, the ratio between the contact surface area and the volume of $10\text{dm}^2/\text{L}$ was used in the overall migration tests, and $6\text{dm}^2/\text{L}$ in the specific migration tests.

The material has been subjected to the corresponding migration tests, which are shown in the test reports TAOHL25007302401 and 70.431.25.16099.01 and are presented below:

1. OVERALL MIGRATION

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

Test conditions: 40°C for 30 minutes

Simulant used	Limit	Unit(s)	RL	A1 (1 st)	Comment
10% Ethanol(V/V)	10	mg/dm ²	3.0	ND	Pass
3% Acetic acid (W/V)	10	mg/dm ²	3.0	ND	Pass

Date: 11/02/2026

2. SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINE

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

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

Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1
3% Acetic acid (W/V)					
Migration times					First
2,4,5-Trimethylaniline	137-17-7	ND	mg/kg	0.002	ND
2,4-Toluenediamine (2,4-TDA)	95-80-7	ND	mg/kg	0.002	ND
2-Methoxy-5-methylaniline	120-71-8	ND	mg/kg	0.002	ND
3,3'-Dimethylbenzidine	119-93-7	ND	mg/kg	0.002	ND
4,4'-Diaminodiphenyl ether	101-80-4	ND	mg/kg	0.002	ND
4,4'-Methylenedianiline	101-77-9	ND	mg/kg	0.002	ND
4,4'-Methylenedi-o-toluidine	838-88-0	ND	mg/kg	0.002	ND
4-Aminobiphenyl	92-67-1	ND	mg/kg	0.002	ND
4-Chloroaniline	106-47-8	ND	mg/kg	0.002	ND
4-Chloro-o-toluidine	95-69-2	ND	mg/kg	0.002	ND
4-Methoxy-m-phenylenediamine	615-05-4	ND	mg/kg	0.002	ND
Benzidine	92-87-5	ND	mg/kg	0.002	ND
o-Anisidine	90-04-0	ND	mg/kg	0.002	ND
o-Toluidine	95-53-4	ND	mg/kg	0.002	ND
2-Naphthylamine	91-59-8	ND	mg/kg	0.002	ND
o-Aminoazotoluene	97-56-3	ND	mg/kg	0.002	ND
3,3'-Dichlorobenzidine	91-94-1	ND	mg/kg	0.002	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	mg/kg	0.002	ND
4,4'-Methylene-bis-(2-chloro-aniline)	101-14-4	ND	mg/kg	0.002	ND
4,4'-Thiodianiline	139-65-1	ND	mg/kg	0.002	ND
4-Amino azobenzene	60-09-3	ND	mg/kg	0.002	ND
1,3-Phenylenediamine	108-45-2	ND	mg/kg	0.002	ND
2-Amino-4-nitrotoluene	99-55-8	ND	mg/kg	0.002	ND
Primary aromatic amine (other)	-	0.01	mg/kg	-	ND
1,3-Diiminoisindoline	3468-11-9	-	mg/kg	0.010	ND
3-Anisidine	536-90-3	-	mg/kg	0.002	ND
2-Amino-1-naphthalenesulfonic acid	81-16-3	-	mg/kg	0.005	ND
2-Ethoxyaniline	94-70-2	-	mg/kg	0.005	ND
5-Chloro-2-methoxyaniline	95-03-4	-	mg/kg	0.005	ND
2-Chloraniline	95-51-2	-	mg/kg	0.010	ND
4-Toluidine	106-49-0	-	mg/kg	0.002	ND
1,4-Phenylenediamine	106-50-3	-	mg/kg	0.002	ND
3-Chloroaniline	108-42-9	-	mg/kg	0.010	ND
3-Toluidine	108-44-1	-	mg/kg	0.002	ND
3-Amino-4-methoxybenzanilide	120-35-4	-	mg/kg	0.002	ND
2-Chloro-4-nitroaniline	121-87-9	-	mg/kg	0.005	ND
4-Chlor-3-methoxyaniline	13726-14-2	-	mg/kg	0.005	ND
4-Ethoxyaniline	156-43-4	-	mg/kg	0.002	ND
3-Amino-4-methylbenzamide	19406-86-1	-	mg/kg	0.002	ND
1,5-Diaminonaphthalene	2243-62-1	-	mg/kg	0.002	ND
4-Aminobenzamide	2835-68-9	-	mg/kg	0.005	ND

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Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1
Aniline	62-53-3	-	mg/kg	0.002	ND
4-Chlor-2,5-dimethoxyaniline	6358-64-1	-	mg/kg	0.005	ND
2,4,5-Trichloroaniline	636-30-6	-	mg/kg	0.010	ND
5-Amino-6-methylbenzimidazolone	67014-36-2	-	mg/kg	0.005	ND
2,6-Diaminotoluene	823-40-5	-	mg/kg	0.002	ND
2,6-Dimethylaniline (2,6-DMA)	87-62-7	-	mg/kg	0.002	ND
4-Aminotoluene-3-sulfonic acid	88-44-8	-	mg/kg	0.005	ND
1,2-Phenylendiamine	95-54-5	-	mg/kg	0.002	ND
2,4-Dimethylaniline (2,4-DMA)	95-68-1	-	mg/kg	0.002	ND
5-Chloro-2-methylaniline	95-79-4	-	mg/kg	0.005	ND
2,5-Dichloroaniline	95-82-9	-	mg/kg	0.010	ND
2,4-Dinitroaniline	97-02-9	-	mg/kg	0.005	ND
2-Methoxy-4-nitroaniline	97-52-9	-	mg/kg	0.005	ND
p-Anisidine	104-94-9	-	mg/kg	0.002	ND
Dimethyl aminoterephthalate	5372-81-6	-	mg/kg	0.002	ND
3,4-Dichloroaniline	95-76-1	-	mg/kg	0.002	ND
1-Naphthylamine	134-32-7	-	mg/kg	0.002	ND
2-Aminobiphenyl	90-41-5	-	mg/kg	0.002	ND
Butyl anthranilate	7756-96-9	-	mg/kg	0.002	ND
2,4'-Diaminodiphenylmethane	1208-52-2	-	mg/kg	0.002	ND
2-Amino-5-methylbenzoic acid	2941-78-8	-	mg/kg	0.002	ND
Comment					Pass

3. SPECIFIC MIGRATION OF HEAVY METALS

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

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

Test Item(s)	Limit	Unit(s)	RL	A1
3% Acetic acid (W/V)				
Migration times				First
Arsenic(As)	ND	mg/kg	0.01	ND
Cadmium(Cd)	ND	mg/kg	0.002	ND
Chromium(Cr)	ND	mg/kg	0.01	ND
Mercury(Hg)	ND	mg/kg	0.01	ND
Lead(Pb)	ND	mg/kg	0.01	ND
Aluminium(Al)	1	mg/kg	0.2	ND
Barium(Ba)	1	mg/kg	0.2	ND
Cobalt(Co)	0.05	mg/kg	0.01	ND
Copper(Cu)	5	mg/kg	1.0	ND
Iron(Fe)	48	mg/kg	9.6	ND
Lithium(Li)	0.6	mg/kg	0.12	ND
Manganese(Mn)	0.6	mg/kg	0.12	ND
Zinc(Zn)	5	mg/kg	1.0	ND

Nickel (Ni)	0.02	mg/kg	0.01	ND
Antimony(Sb)	0.04	mg/kg	0.01	ND
Europium(Eu)	-	mg/kg	0.01	ND
Gadolinium(Gd)	-	mg/kg	0.01	ND
Lanthanum(La)	-	mg/kg	0.01	ND
Terbium(Tb)	-	mg/kg	0.01	ND
Europium (Eu)+ Gadolinium(Gd)+ Lanthanum(La)+ Terbium(Tb)	0.05	mg/kg	-	ND
Comment				Pass

4. SPECIFIC MIGRATION OF BISPHENOL A

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

Method: According to EN 13130-1:2004 and DIN CEN/TS, analysis by HPLC

Test Item(s)	Limit	Unit(s)	RL	A1
3% Acetic acid (W/V)				
Migration times				First
Specific migration of bisphenol A	0.05	mg/kg	0.01	ND
Comment				Pass

5. SPECIFIC MIGRATION OF PHTHALATES

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

Test Item(s)	Result(s) [mg/kg]	Limit [mg/kg]	Conclusion
	002 1 st Migration		
Benzyl Butyl Phthalate (BBP)	<0.05	6	Pass
Di-2-ethylhexyl Phthalate (DEHP)	<0.05	0.6	Pass
Diallyl phthalate (DAP)	<0.01	0.01	Pass
Dibutyl Phthalate (DBP)	<0.05	0.12	Pass
Sum of DIDP+DINP	<1	1.8	Pass
Sum of (DBP*5+DIBP*4+BBP*0.1+DEHP*1)	<0.505	0.6	Pass
Di-(2-ethylhexyl)adipate(DEHA)	<0.05	18	Pass

5.2 Test conditions: 40°C for 30 minutes in 10% Ethanol

Test Item(s)	Result(s) [mg/kg]	Limit [mg/kg]	Conclusion
	002 1 st Migration		
Benzyl Butyl Phthalate (BBP)	<0.05	6	Pass
Di-2-ethylhexyl Phthalate (DEHP)	<0.05	0.6	Pass
Diallyl phthalate (DAP)	<0.01	0.01	Pass
Dibutyl Phthalate (DBP)	<0.05	0.12	Pass
Sum of DIDP+DINP	<1	1.8	Pass
Sum of (DBP*5+DIBP*4+BBP*0.1+DEHP*1)	<0.505	0.6	Pass
Di-(2-ethylhexyl)adipate(DEHA)	<0.05	18	Pass

6. SPECIFIC MIGRATION OF TEREPHTHALATES

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

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

Test Item(s)	CAS No.	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
		002	
Bis(2-Ethylhexyl)Terephthalate 1 st Migration	6422-86-2	<0.05	60
Conclusion		Pass	-

7. SPECIFIC MIGRATION OF ACETYL TRIBUTYL CITRATE

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

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
	002	
Acetyl tributyl citrate 1 st Migration	<10	60
Conclusion	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.

Date: 11/02/2026



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.

The types of food that may come into contact with the gloves covered by this declaration include all aqueous and acidic foods, provided that contact occurs at a temperature below 40 °C and for a maximum duration of 30 minutes. Do not use the glove in contact with fatty foods.

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 or watermark.

Stefan Vintu
Quality and RA Manager

Date: 11/02/2026



ANEX I

COLOR	SIZES			
	S	M	L	XL
TRANSPARENT	GD10NB	GD10NC	GD10ND	GD10NE
BLUE	GD14BB	GD14BC	GD14BD	GD14BE