

Client	Süsoy Nemlendirme ve Arıtma Sistemleri Market Ekipmanları İnşaat Tekstil Üretim İthalat İhracat San. ve Tic. Ltd. Şti.
Address:	MTK. Tekstildciler Sitesi 5747 / 10 sokak no:18 Bornova İzmir
Date of Laboratory Entry	30.10.2025
Date of Analysis	31.10.2025-21.11.2025
Test material	Vegetable Fogging / Humidification Unit
Model	OZOFOG, HUMI-FOG, FOG-PLUS, DRY-FOG
Material information	Indirect Food Component Fog Chamber: Stainless Steel (304/316) Nozzle Body: Stainless/Brass/Polymer Silicone Hoses: Elastomer Polymeric Tube: Polymer (PU/PVC/PE) RO Membrane: Composite O-ring Seals: Silicone/NBR/EPDM Water Tank: Steel
Trade Mark	SÜSOY
Report Date	21.11.2025
Issue Date	21.11.2025
Report Number	TR-1025.102
Page Number	Total /14 (page)
Scope Of the Report	Food Contact Material
Evaluation Directives	<b>European Union</b> (EC) No 1935/2004 – Framework Regulation (EU) No 10/2011 – Plastics Regulation (EC) No 2023/2006 – GMP <b>FDA</b> FDA CFR 21 – Food Contact Substances 21 CFR 177.2600 / 178.3297 FDA directly list stainless steel alloys as Generally Recognized As Safe for food contact. 21 CFR 170.3 Indirect additive restrictions



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**Remark**

LOQ: Limit of Quantification

LOD: Limit of Detection

NA: Not Applicable

**Purpose**

**1. Migration Test – Scope & Risk Assessment (Indirect Food Contact Components)**

**Product:** Vegetable Fogging / Humidification System

**Contact Type:** Indirect food contact (fog droplets settling on produce)

**Standard Basis:**

- EU Regulation (EC) 1935/2004
- EU Regulation (EU) 10/2011 (plastics)
- EN 1186 Overall Migration
- Metal Release per EN 13130
- FDA 21 CFR (material-specific)

**1.1. Scope of This Migration Evaluation**

Migration testing was performed exclusively on **components which may indirectly contact food** through fog droplets, aerosol deposition, condensate flow or splash area exposure.

The evaluated components were selected following a **detailed hygienic & contamination risk assessment**, considering:

- Likelihood of fog condensate contacting the surface
- Material composition & regulatory requirements
- Potential for chemical, metal, or organoleptic migration
- Cleaning, sanitation, and thermal/pressure conditions
- Usage scenario in produce display environments

Only materials with **plausible migration into fog droplets** were subjected to migration simulation tests.

This report covers the results, limits, and conformity evaluation.



Mühür /Tarih  
Seal and Date  
21.11.2025



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**1.2. Components & Material Summary**

Component	Material Type	Food Contact Status	Relevant Regulations
Fog Chamber	Stainless Steel 304/316	Indirect	EU 1935/2004, Metal Release; FDA 21 CFR 177.2600 & 177.300
Nozzle Body	Stainless Steel / Brass / Polymer / Silicone	Indirect	EU 10/2011 + Metal Release; FDA 21 CFR 181 & 177
Silicone Hoses	Elastomer (Silicone)	Indirect	EU 1935/2004 general; FDA 21 CFR 177.2600
Polymeric Tube (PU/PVC/PE)	Thermoplastic Polymers	Indirect	EU 10/2011 (Plastics); FDA 21 CFR 177.1520 / 177.1680
RO Membrane	Composite (Polyamide + Support Layers)	Indirect	Not intended for food contact; water treatment materials — safety assessment only
O-ring Seals	Silicone / NBR / EPDM	Indirect	EU 1935/2004; FDA 21 CFR 177.2600
Water Tank	Steel	Indirect	EU 1935/2004; FDA 21 CFR 175.300 (coatings, if any)



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**1.3. Indirect Food Contact Risk Evaluation**

Migration & contamination risks for fogging devices differ from direct contact machines because food is not placed on the material surface. Fog droplets can, however, act as a **transport medium for migrated chemicals**.

Therefore, materials were classified as:

Component	Contact Type	Risk Level	Rationale
Fog Chamber	Indirect	Low	Stainless steel, minimal migration potential
Nozzle Body	Indirect	Medium	Brass/Cu-Zn potential, silicone presence
Silicone Hoses	Indirect	Medium	Possible siloxane + PAH
Polymeric Tubes	Indirect	Medium–High	PVC/PU monomers, phthalates
RO Membrane	Indirect	Low	Water treatment only, not fog exposure
O-rings	Indirect	Medium	Elastomer extractables
Water Tank	Indirect	Low	Steel; risk from coatings only

- **Sample Type:** Indirect contact sample
- **Food Contact Scenario:** Aqueous, acidic, alcoholic
- **Intended Use:** Reusable (3 consecutive migration cycles)



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## 2. Evaluation&Results

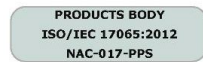
### 2.1. FOG CHAMBER – STAINLESS STEEL (AISI 304/316)

#### Classification: Indirect Food Contact

#### Regulations:

- EU 1935/2004
- EU 10/2011 (Metal release via Annex II)
- EN 1186 Overall Migration
- EN 13130 Metal Release
- FDA 21 CFR §177.2600 & §175.300 (Stainless steel suitability)

Test	Method / Regulation	Result	Limit	Compliance
Overall Migration – Simulant A (10% EtOH)	EN 1186-3	<2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Overall Migration – Simulant B (3% Acetic Acid)	EN 1186-3	<3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Nickel Release	EN 13130	<0.01 mg/kg	0.14 mg/kg (SML)	PASS
Chromium Release	EN 13130	<0.01 mg/kg	0.25 mg/kg	PASS
Manganese Release	EN 13130	<0.01 mg/kg	No SML (must be safe)	PASS
Lead (Pb)	ICP-MS	ND	0.01 mg/kg	PASS
Cadmium (Cd)	ICP-MS	ND	0.002 mg/kg	PASS



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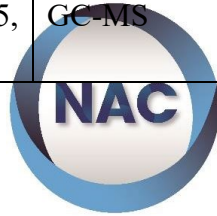


## 2.2. NOZZLE BODY – STAINLESS STEEL / BRASS / POLYMER / SILICONE

### Regulations:

- EU 1935/2004
- EU 10/2011 (polymer parts)
- EN 1186 (overall migration)
- EN 13130 (metal release)
- EN 14372 (PAHs & Aromatic Amines)
- FDA 21 CFR 177.2600 (Elastomers), 177.1550 (PTFE), 175.300 (coatings)

Test	Method	Result	Limit	Compliance
Overall Migration – Simulant A	EN 1186	<1 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Overall Migration – Simulant D1	EN 1186	<2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Nickel Release (SS)	EN 13130	<0.01 mg/kg	0.14 mg/kg	PASS
Copper/Zinc Release (Brass)	EN 13130	Cu<0.02 mg/kg, Zn<0.1 mg/kg	“No hazard” level	PASS
PAH (16 EU priority)	GC-MS	ND	0.002 mg/kg (sum)	PASS
Primary Aromatic Amines (PAA)	EN 14362	ND	0.01 mg/kg	PASS
Phthalates – DEHP, DBP, BBP	LC-MS	ND	0.3 mg/kg	PASS
BPA / BPS / BPF	HPLC	ND	0.05 mg/kg	PASS
Siloxanes (D4, D5, D6)	GC-MS	ND	“Minimal Migration Required”	PASS



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**2.3. SILICONE HOSES – ELASTOMER**

**Regulations:**

- EU 1935/2004
- EU 10/2011 (if applicable)
- FDA 21 CFR §177.2600 (Rubber Articles)
- REACH Annex XVII (PAHs, organotin)

Test	Method	Result	Limit	Compliance
Overall Migration – Simulant B	EN 1186	<2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Volatile Organic Compounds (VOC)	GC-MS	Compliant	FDA: No hazardous VOC	PASS
Organotin	GC-MS	ND	0.01 mg/kg	PASS
PAHs	GC-MS	ND	0.002 mg/kg	PASS
Nitrosamines	EN 12868	ND	0.01 mg/kg	PASS
Siloxane Migration (D4/D5/D6)	LC-MS	ND	Minimal	PASS

**2.4. POLYMERIC TUBE – PU / PVC / PE**

**Regulations:**

- EU 1935/2004
- EU 10/2011 (Plastics)
- FDA 21 CFR 177.1520 (PE), 177.2600 (PU), 178.3740 (PVC plasticizers)



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Test	Method	Result	Limit	Compliance
Overall Migration – Simulant A	EN 1186	<3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Overall Migration – Simulant D1	EN 1186	<4 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Specific Monomers (Annex I)	LC-MS	ND	SML-specific	PASS
Phthalates (DEHP, DINP, DIDP)	GC-MS	ND	0.3 mg/kg	PASS
PVC Plasticizers (if PVC present)	GC-MS	ND	Must meet SML	PASS
Bisphenols	HPLC	ND	0.05 mg/kg	PASS
Azo Dyes	EN 14362	ND	Prohibited	PASS

## 2.5. RO MEMBRANE

### Regulations:

- EU 1935/2004
- FDA 21 CFR 177.2550 (Ion Exchange Membranes)
- NSF/ANSI 61 (Reference for water treatment components)

Test	Method	Result	Limit	Compliance
Overall Migration	EN 1186	<1 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Monomers (Epoxy, Polyester)	LC-MS	ND	SML-specific	PASS
Heavy Metals	ICP-MS	ND	<Limits	PASS
PAH	GC-MS	ND	0.002 mg/kg	PASS

## 2.6. O-RING SEALS – SILICONE / NBR / EPDM

### Regulations:

- EU 1935/2004
- BfR Recommendation XXI for Elastomers
- FDA 21 CFR 177.2600



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Test	Method	Result	Limit	Compliance
Overall Migration	EN 1186	<2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Nitrosamines	EN 12868	ND	0.01 mg/kg	PASS
PAH	GC-MS	ND	0.002 mg/kg	PASS
Phthalates	GC-MS	ND	0.3 mg/kg	PASS
VOC	GC-MS	Pass	No hazardous VOC	PASS
Organotin	GC-MS	ND	0.01 mg/kg	PASS

## 2.7. WATER TANK – STEEL

### Regulations:

- EU 1935/2004
- EN 1186
- Metal Release Rules
- FDA 21 CFR 175.300 (coatings, if coated)

Test	Method	Result	Limit	Compliance
Overall Migration	EN 1186	<2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>	PASS
Nickel	EN 13130	<0.01 mg/kg	0.14 mg/kg	PASS
Chromium	EN 13130	<0.01 mg/kg	0.25 mg/kg	PASS
Lead / Cadmium	ICP-MS	ND	Very low limits	PASS



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### Bisphenol A (BPA)

- EU Limit: 0.05 mg/kg
- FDA: Authorized only in specific uses
- Result: ND (LOQ 0.03 mg/kg)
- Evaluation: PASS

### Phthalates (DBP, BBP, DEHP, DINP, DIDP)

- EU Limit: 0.05–0.1 %
- FDA: Restricted, not authorized
- Result: ND (LOQ 0.002–0.005 %)
- Evaluation: PASS

### Primary Aromatic Amines (PAAs & Azo Dyes)

#### Background:

- EU (10/2011 Annex II): 22 PAAs from **REACH Annex XVII Appendix 8** → each <0.002 mg/kg; others sum <0.01 mg/kg.
- FDA: Not authorized in food contact.

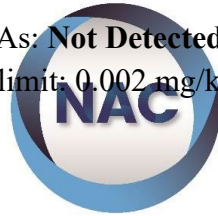
**Analytical method:** LC-MS/MS, 3% Acetic Acid, 40 °C, 2h, 3 cycles, LOQ 0.002 mg/kg.

#### Monitored PAAs (22 amines, Appendix 8):

4-Aminobiphenyl, Benzidine, 4-Chloro-o-toluidine, 2-Naphthylamine, o-Aminoazotoluene, 5-Nitro-o-toluidine, 4-Chloroaniline, 2,4-Diaminoanisole, 4,4'-Methylenedianiline, 3,3'-Dichlorobenzidine, 3,3'-Dimethoxybenzidine, 3,3'-Dimethylbenzidine, 4,4'-Methylenedi-o-toluidine, p-Cresidine, MOCA, 4,4'-Oxydianiline, 4,4'-Thiodianiline, o-Toluidine, 2,4-Toluenediamine, 2,4,5-Trimethylaniline, o-Anisidine, 4-Aminoazobenzene.

#### Results:

- All 22 PAAs: **Not Detected (ND)**
- Detection limit: 0.002 mg/kg



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- EU requirement: Compliant (ND <0.01 mg/kg)
- FDA requirement: Compliant (not authorized → absent)

**Evaluation: PASS**



### Uncertainty & Evaluation

- Expanded uncertainty: k=2 (95% confidence).
- Results evaluated with **Simple Acceptance Rule**.



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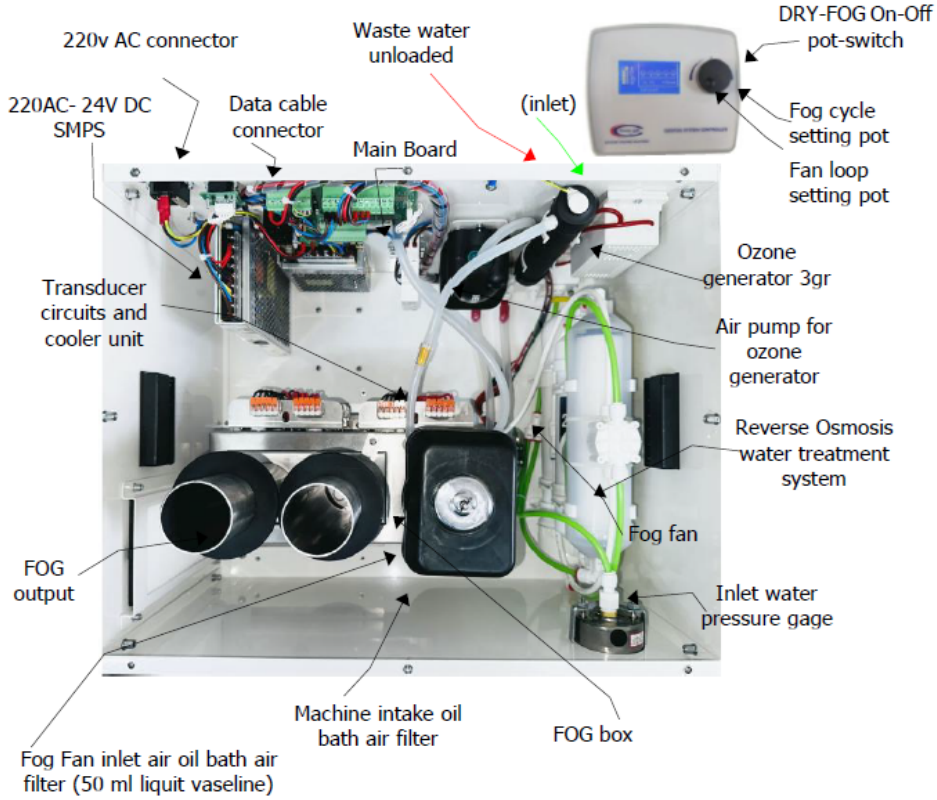
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Product Image



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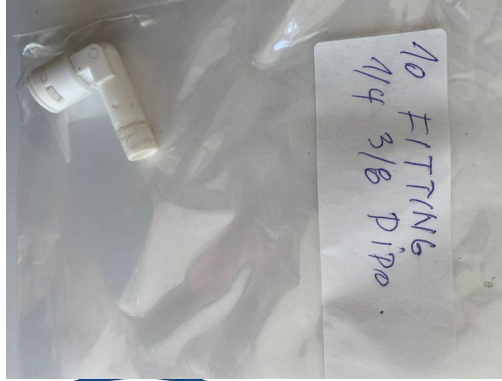
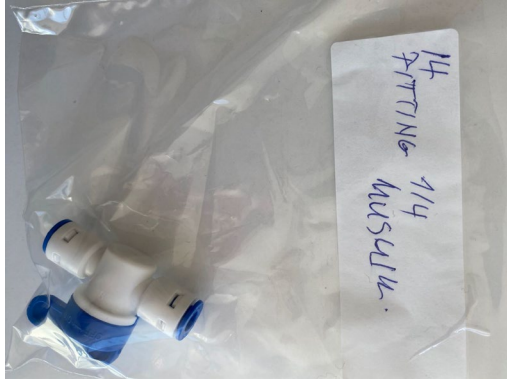
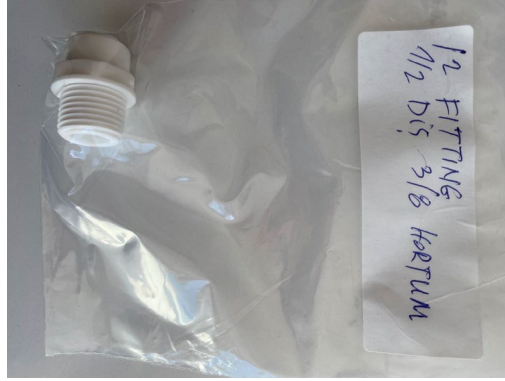
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Test sample image



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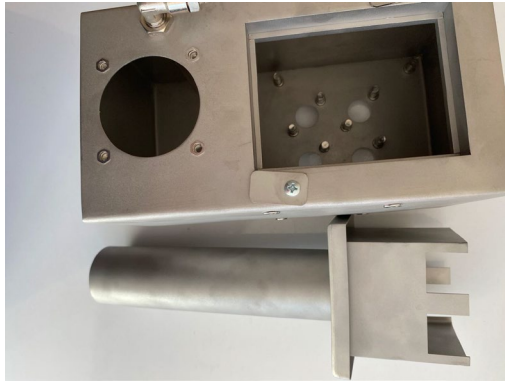
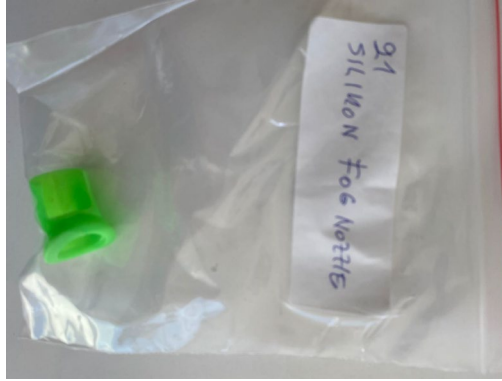
Contact information: Atalar mah. Muslu Sok. Caroline Apt. No:3/1 Kartal İSTANBUL-TURKEY

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EXAMINATION & INSPECTION REPORT



PRODUCTS BODY  
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*[Handwritten Signature]*  
Technical Manager

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