

 <small>Italian Hoses &amp; Gaskets Since 1977</small>	<b>PTFE HOSES</b> <b>Food Contact Report</b>	<b>Palazzolo S/O</b> <b>11/09/2025</b>
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## PRODUCT DESCRIPTION

## ITG HOSEFLON® PTFE – Tubing for food zone

ITG srl has submitted its PTFE hoses to a test program in order to assess the compliance with the main international regulations on food contact.

All the test results are in compliance with the restrictions as defined in the following regulations:

- **Regulation (EU) No. 10/2011 and 2020/1245 according to Regulation CE 1935/2004;**
- **FDA 21 CFR 177.1550;**
- **GB Standard 4806.6-2016, 4806.7-2016 e 9685.**

In the following paragraphs you can find a resume of the integrated analytical plan to which our product has been submitted. Tests in common to different regulations have not been repeated.

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**ITG SPA** | Italian Hoses & Gaskets Since 1977

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## 1. DM 21/03/1973 and amendments

Hygiene rules for packaging, containers and utensils intended to come into contact with foodstuffs or personal use products. Since the beginning of 2019, Italy's Ministry of Health has published two amendments to its Decree of the Minister for Health of March 21, 1973 on 'Hygiene rules for packaging, containers and utensils intended to come into contact with foodstuffs or personal use products' (Ministerial Decree 3.21.1973). These revisions are under the following pieces of legislation:

- Decree No. 30 of February 7, 2019 amending 'Annex II Section 1: Plastics, Part A – Resins' by adding N, N, N', N'-tetrakis(2-hydroxyethyl) adipamide as a new entry for certain uses to the authorized list of substances for the preparation of articles intended to come into contact with food. This became effective on April 24, 2019
- Decree No. 72 of May 9, 2019 amending Section 6 to Annex II by expanding the list of authorized food contact stainless steels from 42 to 50 and updating the list of unintentionally added elements that are allowed. These became effective on August 16, 2019

TEST DESCRIPTION	LAW REF
<ul style="list-style-type: none"><li>- Specific migration of colourings in acetic acid 3%w/v</li><li>- Specific migration of colourings in ethanol 10%v/v</li><li>- Specific migration of colourings in sunflower oil</li></ul>	DM 21/03/1973 SO GU n°104 20/04/1973 and amen.

## 2. Regulation (EC) No. 1935/2004

This Framework Regulation aims to ensure that "any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties."

TEST DESCRIPTION	LAW REF
<ul style="list-style-type: none"><li>- Screening HS GC-MS volatile organic substances_30 min 120°C</li><li>- Screening GC/MS of semi-volatile substances in ethanol 95%</li><li>- Screening HPLC/QTOF of non volatile substances in ethanol 10%</li><li>- Evaluation of organoleptic inertia (flavour) - No packaging</li><li>- Evaluation of organoleptic inertia (odour) - No packaging</li></ul>	Reg. CE 1935/2004

## 3. Regulation UE 10/2011 and amendment 2020/1245

Regulation (EU) 10/2011 sets out safety requirements for plastic materials and articles intended to come into contact with food. This regulation is a specific measure for plastic food contact materials as mentioned in the European Framework Regulation (EU) 1935/2004.

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On September 3, 2020, the European Union (EU) published Regulation (EU) 2020/1245 to amend and correct Regulation (EU) 10/2011.

TEST DESCRIPTION	LAW REF
<ul style="list-style-type: none"> <li>- Primary aromatic amines in acetic acid 4%</li> <li>- Global migration in acetic acid 4%</li> <li>- Overall migrations in ethanol 10%</li> <li>- Overall migration in ethanol 95%</li> <li>- Overall migrations in isooctane</li> <li>- Specific Migration of 1,4-Aminobiphenyl_CAS 92-67-1</li> <li>- Specific Migration of Benzidine_CAS 92-87-5</li> <li>- Specific Migration of 4-chloro-o-toluidine_CAS 95-69-2</li> <li>- Specific Migration of 4-chloroaniline_CAS 106-47-8</li> <li>- Specific Migration of 2,4-diaminoanisole_CAS 1615-05-4</li> <li>- Specific Migration of 4,4'-diaminodiphenylmethane_CAS 101-77-9</li> <li>- Specific Migration of 3,3'-dimethoxybenzidine_CAS 119-91-4</li> <li>- Specific Migration of 3,3'-dimethylbenzidine_CAS 119-93-7</li> <li>- Specific Migration of 3,3'-dimethyl-4,4'diaminodiphenylmethane_CAS 838-88-0</li> <li>- Specific Migration of p-cresidine_CAS 120-71-8</li> <li>- Specific Migration of 4,4'-oxydianiline_CAS 101-80-4</li> <li>- Specific Migration of 4,4'-thiodianiline_CAS 139-65-1</li> <li>- Specific Migration of O-toluidine_CAS 95-53-4</li> <li>- Specific Migration of 2,4-toluylenediamine_CAS 95-80-7</li> <li>- Migration of 2,4,5-trimethylaniline_CAS 137-17-7</li> <li>- Specific migration of o-Anisidine_CAS 90-04-0</li> <li>- Specific Migration of 4-aminoazobenzene_CAS 60-09-3</li> <li>- Specific Migration of aniline_CAS 62-53-3</li> <li>- Specific Migration of m-phenylenediamine_CAS 823-40-5</li> <li>- Specific Migration of p-phenylenediamine_CAS 823-40-5</li> <li>- Specific Migration of 2,6-toluylenediamine_CAS 823-40-5</li> <li>- Specific Migration of 2,4-dimethylaniline_CAS 95-68-1</li> <li>- Specific Migration of 2,6-dimethylaniline_CAS 87-62-7</li> <li>- Specific migration of 14 heavy metals in 4% acetic acid</li> <li>- Specific migration of 4 lanthanides metals in acetic acid 4%</li> <li>- Specific migration of Tetrafluoroethylene CAS 116-14-3</li> </ul>	Reg UE 10/2011 and amendment 2020/1245

#### 4. FDA 21 CFR 177.1550

The Federal Food, Drug and Cosmetic Act (FD&C Act) from 1958 is the basic regulation governing food contact materials, which are regulated in the Code of Federal Regulations (C.F.R.) under Title 21, Parts 174-186. They may also fall under further specific regulations depending on their use. Clearance for food contact materials is required for those that are considered additives, also referred to as indirect additives, which are those that can reasonably be expected to migrate into the foodstuff. The parts in Title 21 list specific conditions that must be met by the substances and may also include positive lists of substances.

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TEST DESCRIPTION	LAW REF
<ul style="list-style-type: none"><li>- Extractable fraction in n-heptane 2 hours reflux</li><li>- Extractable fraction in ethanol 50% 2 hours reflux</li><li>- Extractable fraction in distilled water 2 hours reflux</li><li>- Fluoride extractives in distilled water 2h at reflux</li><li>- Extractable fraction in Ethyacetate 2 hours reflux</li></ul>	Code of Federal Regulations Title 21 Part 177 Sec. 177.1550 Perfluorocarbon resins

## 5. GB 4806.6-2016, GB 4806.7-2016 and 9685

China's National Food Safety Standards **GB 4806.6-2016, GB 4806.7-2016 and 9685** govern the use of plastics and polymers in food contact materials.

TEST DESCRIPTION	LAW REF
<ul style="list-style-type: none"><li>- Sensory inspection, Colour and Luster, Abnormal odour and dirt, Soak Solution condition, Coloration, Abnormal Odour, Precipitation, Turbidity</li><li>- Potassium Permanganate Consumption</li><li>- Heavy Metals (in Pb) 4% acetic acid</li><li>- Decolorization test</li></ul>	GB 4806.11-2016 GB 4806.6-2016

## 6. Conclusions

All the test results are in compliance with the restrictions as defined in the aforementioned international standards on food contact. All the tests have been carried out by an accredited laboratory. No contaminants of any kind are intentionally added to the product during the production or packaging phases. The full test report text is available on specific request.

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