



TECHNISCHE SCHLÄUCHE
INDUSTRIAL HOSES

GUMEX

Manufacturer FDA certification according to PUR-MHF

Here: AIRDUC PUR 351 MHF, 351-xxxx-0000

Polyurethane hoses of the NORRES PUR MHF series, which are made from special, particularly high-quality raw materials, are perfectly suited for many applications in the food sector. This product series includes the following hose types among others, in the standard make ... 0000 and ..1001 with transparent, not colored wall:

- PROTAPÉ® PUR 331 MHF
 - PROTAPÉ® PUR 330 MHF
 - PROTAPÉ® PUR 335 MHF FLAT
 - AIRDUC® PUR 351 MHF
 - AIRDUC® PUR 355 MHF
 - AIRDUC® PUR 356 MHF
 - AIRDUC® PUR 356 MHF reinforced
 - BARDUC PUR INOX 382 MHF
 - CP PUR INOX 455 MHF
 - NORFLEX®PUR 401 MHF
 - NORFLEX®PUR 441 MHF
- and
- PROTAPÉ® PUR INOX 330 MHF
 - PROTAPÉ® PUR-CU 335 MHF FLAT
 - AIRDUC® PUR INOX 351 MHF
 - AIRDUC® PUR INOX 355 MHF
 - AIRDUC® PUR INOX 356 MHF

These hose types have officially legal and regulatory approvals for food applications by independent institutes, complying with many of the food industry guidelines, and they can also be used with some restrictions in the medical sector.

The properties of the material used for the hose wall include the following:

- **Compliance with FDA (US Food and Drug Administration) regulations:**
The raw materials and additives used (except for stabilizers) are listed in the FDA CFR Title 21 § 177.2600 "Rubber articles intended for repeated use" dated April 1, 2010. The antioxidants and stabilizers used are listed in § 178.2010 "Antioxidants and/or stabilizers for polymers".
- **BfR (German Federal Institute for Risk Assessment, formerly BqVV):**
The monomers used in manufacture are listed in the **German Commodities Ordinance (BGVO)** published December 23, 1997 (BGBl. 1998 I, p. 5), last changed on July 2, 2010.
The used initial substances are listed in Section 2.1, Category 1 of **Recommendation XXXIX, "Commodities based on Polyurethanes"** BfR from June 1, 1998, last changed on January 1, 2010
- **EC Regulation 2002/72/EC and 10/2011**
The monomers and additives used are listed in the appendices of the **Regulation 2002/72/EEC** corresponding to the version after the latest regulation amendment **2007/19/EC and 2008/39/EC, EC-Regulation 975/2009 and regulation 10/2011**, as well as amendment regulation **1183/2012**.

When we label hoses with the official food logo of the EU, the "glass/fork" symbol, we have an official approval for the **entire hose** in each case by an **independent testing laboratory** in accordance with the **EU Regulation 2002/72/EC, incl. Regulation 975/2009 and Regulation 10/2011**.

The examinations carried out by an independent testing laboratory show that these product lines meet the requirements of the **EU Regulation 2002/72/EC, incl. 975/2009 and Regulation 10/2011**, relating to plastic materials and articles intended to come into contact with foodstuffs and the **German BGVO** for food contact articles. Please note the official test certificate.

(Note: Some of the guidelines for food contact cited above, which are based on EU Directives, lists limitations of the residual content of individual components of synthetic materials. However, it should be noted that the regulation 10/2011, which applies to all EU member states, sets a limit value for the overall constituent migration in synthetic products for food sector use of 10 mg/dm². Even if, as in this case, an official statement from the manufacturer is available, according to Directive 10/2011, these tests should be performed on the end product by the processor using the corresponding foods or food simulation materials. Times and temperatures should be chosen to reflect actual conditions during the normal use of the articles, in accordance with the rule from EU regulation 10/2011. It is the responsibility of the processor to ensure that the article is suitable for the intended purpose.)

Best regards,
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