



## DECLARATION OF COMPLIANCE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

1. We hereby certify that the supplied hose REFITTEX CRISTALLO produced by:

Fitt S.p.A. Via Piave, 8 36066 Sandrigo, VI (Italy) Tel. +39 0444 46 10 00 Fax +39 0444 46 10 99
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### complies

with all relevant regulations, and particularly with the following:

- Regulation 1935/2004/EC,
- Regulation EC 2023/2006 (GMP),
- Regulation (EU) 10/2011 and following revisions and amendments,

and with the following Italian Regulations:

- D.M. 21/03/1973 and following revisions and amendments,
- DPR 777/82 and following revisions and amendments.

2. The above mentioned product is manufactured with the following materials suitable for food contact:

- Inside layer made of PVC plasticized (contact side).
- Reinforcement in polyester thread.
- Outside layer made of PVC plasticized.

3. The following substances subject to restrictions and/or specifications are used in the above mentioned products:

Substance name	Ref. No	CAS No	SML [mg/kg]	Group restriction No	Restrictions and specifications
Terephthalic acid, bis(2-ethylhexyl) ester	92200	0008422-88-2	LMS = 60 mg/Kg	(32)	-
Soybean oil, epoxidised	88640	0008013-07-8	LMS = 60.0mg/Kg LMS = 30.0 mg/Kg*	-	(*) In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC, the SML is lowered to 30 mg/kg. Oxirane < 8 %, iodine number < 6.
Polyethylene w axes, oxidised	80077	0088441-17-8	LMS = 60 mg/Kg	-	-
Calcium salts of fatty acid	-	-	-	-	no SML, DUAL USE (art. 11 3a)
Zinc salts	-	-	LMS = 5mg/Kg as Zinc	-	-
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	0002082-79-3	LMS = 6mg/Kg	-	-
Vinyl chloride	28050	0000075-01-4	ND*	-	(*) 1 mg/kg in final product

Table 1

4. To the best of our knowledge we can confirm that there are some Dual Use Additives present in the product as described in the table above (Table 1) and that the product doesn't contain "Non Intentionally Added Substances" (NIAS).



5. We certify that:

- The article meets the overall migration limits and specific migration limits under the following test conditions:
  - Simulant A: AQUEOUS SOLUTION OF ETHANOL at 10% v/v (for aqueous foodstuffs).  
Testing time and temperature: 10 days at 40°C
  - Simulant B: AQUEOUS SOLUTION OF ACETIC ACID at 3% p/v (for acid foodstuffs).  
Testing time and temperature: 10 days at 40°C
  - Simulant C: AQUEOUS SOLUTION OF ETHANOL at 20% v/v (for alcoholic foodstuffs).  
Testing time and temperature: 10 days at 40°C
  - Simulant D1: AQUEOUS SOLUTION OF ETHANOL at 50% v/v (for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions and milk).  
Testing time and temperature: 3x2 hours at 40°C, for repeated use.

The product complies with the overall migration limits and other specific restrictions under which the monomers and/or additives contained in the material can be submitted, at the abovementioned usage conditions. All declared is supported by analytical tests carried out in compliance with the DM 21/03/1973 and articles 17 and 18 of Regulation (EU) 10/2011 in conjunction with Annex V or based on calculations made taking into account the % of the substances submitted to migration limits in the test conditions. Calculations presume that 1 kg of food enters into contact with 6 dm<sup>2</sup> of product. We remind that the Migration Limit is 60 mg/Kg food [ppm], also expressed as 10 mg/dm<sup>2</sup> (if the certificate reports mg/kg it is possible to convert it into mg/dm<sup>2</sup> dividing the value by 6) and we underline that the change in the analytical tolerance is between 10 and 20% (12 mg/kg or 2 mg/dm<sup>2</sup>).

6. We suggest giving notice to the writing Society if the usage conditions of the product do not correspond to the advice here supplied or whether the foodstuff which come into contact with the product (Food Contact Material) is different from the applicable conditions and from the simulants listed above.
7. The user of the product which is intended to come into contact with food has the responsibility of informing the writing Company about any restriction due to particular component characteristics (additives and aromas) of the foodstuff which has to be transported.
8. Industrial or commercial usage of the product concerned in this declaration is subject to the evaluation of its compliance to actual regulations and to the technological suitability to the declared final usage.
9. This declaration is valid as from the date indicated below and will be renewed when substantial changes in the processing (final product/raw material) will bring about modifications in some necessary requirements or when new amendments to the regulations mentioned at point 1) will require new controls to verify the compliance.
10. Moreover, we inform that all necessary support documents are at the disposal of the control authorities, in accordance with art. 16, par. 1 of Regulation 1935/2004/EC.

Date: 02 / 12 / 2020

*This document and its attachments are addressed solely to the person or company above and contain confidential information.*

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