


ALFAGOMMA

WE HEREBY DECLARE THAT THE
TUBE COMPOUND OF FOLLOWING HOSES



// 4660L

**General Purpose S&D - PVC – Standard Duty
FDA EU 10/2011 A+B+C - AS 2070**

 We hereby declare that the ALFAGOMMA hose 4660L – General Purpose S&D – PVC – Standard Duty is suitable to be used with the following products:

- ◆ Aqueous food;
- ◆ Moist food products with pH > 4,5 and food products containing alcohol up to 10%;
- ◆ Acid food products with pH < 4,5;
- ◆ Food products containing alcohol up to 20% and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

In particular the hose is suitable for contact with aqueous foods, acid and alcohols (up to 20%) for which there are simulants A,B and C for repeated contact of up to 10 days at a maximum temperature of 40°C

(For the designation of the food we chose the product or classes from the group categories listed in Directive 85/572 /EEC), adopted by the Ministerial Decree No. 220 of 26/04/1993 and later updates and amendments – see note at the end of the document on the Article 23 of Reg (EU) No. 10/2011).

In compliance with the following EU legislations:

- ◆ Regulation (EC) No. 1935/2004;
- ◆ Regulation (EU) No. 10/2011 and subsequent updates and amendments;
- ◆ Regulation (EC) No. 2023/2006;

The hoses contains the following substances, called “dual use”, governed by Regulation (EC) n°1333/2008 and 1334/2008 and subsequent amendments:

- ◆ E479b Thermally Oxidised Soya Bean Oil Interacted with Mono and Diglycerides of Fatty Acids;
- ◆ E470a Sodium, Potassium and Calcium Salts of Fatty Acids;
- ◆ E914 Oxidized Polyethylene wax;
- ◆ E905 Microcrystalline wax.

The above hose is manufactured exclusively with substances (monomers, pigments and additives) listed in the positive lists contemplated by the European Reg. 10/2011.

The above hose contains substances subjected to restrictions in the afore mentioned laws which are listed below:

Name	No. Ref.	No. CAS	Type of limit and value	Restrictions and/or specifications
Salts (including double salts and acid salts) of zinc of authorized acids	-	-	SML = 25mg/Kg expressed as zinc	-
polyethylene waxes, oxidised	80077	0068441-17-8	SML = 60 mg/Kg	-
Soybean oil epoxidised	88460	008013-07-8	SML = 60.0 mg/Kg	SML = 30 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.
terephthalic acid, bis(2-ethylhexyl)ester	92200	006422-86-2	SML = 60.0 mg/Kg	SML (T) = 60 mg/kg
Calcium salt or fatty acids	-	-	-	No SML but calcium salts or fatty acids to be considered as Dual Use (art. 11 3a)
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	2082-79-3	SML = 6mg/Kg	-

Test Conditions:

Simulant A: ethanol 10%	Time and Temperature: 10 days at 40°C
Simulant B: Acetic Acid 3%	Time and Temperature: 10 days at 40°C
Simulant C: Ethanol 10%	Time and Temperature: 10 days at 40°C

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The overall migration limit, together with other specific restrictions to which the monomers and / or additives present in the material may be subjected, are met in the above conditions of use.

This declaration is addressed to all companies, organizations, users who use the above mentioned product within the fields of application defined in the declaration itself.

The user of the hose intended for contact with food is responsible for informing the company in writing of any restriction due to the characteristics of the ingredients (presence of additives and flavourings) of the food product to be transported.

 In Addition We declare that the ALFAGOMMA hose 4660L – General Purpose Food Quality – PVC is produced with polyvinylchloride compounds containing additives that, following FDA criteria, can be considered as:

- ◆ Substances generally recognized as safe in or on food;
- ◆ Substances generally recognized as safe for their intended using in food packaging;
- ◆ Substances used in accordance with a prior sanction or approval;
- ◆ Substances permitted for use by regulations in this part and part 175, 176, 177, 178 of this chapter.

Substances which must comply with a specific migration limit: none

Limitations:

- ◆ In contact with food of types I, II, III, IV, V, VI, VII, VIII and IX described in table 1 of 176.170 (c) of this chapter under conditions of use A through H described in table 2 of 176.170 (c) of this chapter at temperatures not to exceed 88°C (190°F).

We remind that it is responsibility of the final user to verify the reciprocal compatibility of the hose and of the foodstuff, and to verify the absence of organoleptic modifications of the abovementioned foodstuff.

This declaration is valid from the date above and will be substituted in advance in the event of changes in production / formulation of the material or if the legislative references are modified and updated so as to require a new check for compliance.

Industrial Hose Division
Factory Quality Manager
Quinto Piccioni



Date: 16/05/2017