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Wednesday, January 18, 2023

DECLARATION OF CONFORMITY

To whom this may concern,

We hereby declare the hoses:

SR13 & SR19

are suitable for contact with aqueous food, acid and alcohol (up to 20%) for which A, B and C simulants are provided, for a maximum of 2 hours repeated contact at the maximum temperature of 70°C.

The hoses are devices suitable for the passage of fluids and therefore should not be used for food storage. Avoid contact of food with the heads and outer surface of the hoses. The hoses must be sterilised prior to use by the end user.

The hoses are made of soft PVC, with polyester yarn reinforcement (single or double reinforcement) and an intermediate TPU layer.

In compliance with the following EU legislation:

- Directive EEC no. 1978/142
- Regulation (EC) no. 1935/2004
- Regulation (EC) no. 1895/2005 (epoxy derivatives)
- Regulation (EC) no. 2023/2006 (GMP)
- Regulation (EC) no. 10/2011 and subsequent amendments

and the following Italian legislation:

- Ministerial Decree 21/03/1973 and subsequent amendments and changes
- Presidential Decree 777/82 and subsequent amendments and changes

The SR13 & SR19 hoses are manufactured exclusively with substances (monomers, pigments and additives) indicated in the positive lists of the above legislation. The material contains substances subject to restrictions in the laws mentioned and listed below:

Substance	Ref. No.	CAS No.	SML (mg/kg)
Vinyl chloride	26050	75-01-4	0.01
Phthalic acid diesters with primary, saturated C 8-C 10 branched alcohols, more than 60% C 9	75100	68515-48-0 28553-12-0	9
Soybean oil, epoxidised	88640	8013-07-8	60
Titanium dioxide	93440	13463-67-7	---
Zinc salts	--- (*)	---	5

(*) Annex II reg. UE 10/2011.

Test conditions:

Simulant:

B: acetic acid at 3% in aqueous solution

C: ethanol at 20% in aqueous solution

Time and temperature:

2 hours at 70°C (repeated use)

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The simulants and test conditions were chosen according to Regulation (EU) n. 10/2011 (annex III tab. 1 and annex V tab.3) subsequent updates.

The analytical tests were conducted in accordance with Regulation 1935/2004/EC, Regulation 10/2011/EU and Italian Ministerial Decree (D.M.) 21/03/1973 on the liquid coming from contact with a representative sample in modality "Article Filling" with maximum contact surface I volume ratio of 3,17 (dm²/dl) (simulant B,C) respecting the test conditions mentioned above. To verify compliance with regulations, the calculations were made assuming that 1 kg of food comes into contact with 6 dm² of material.

According to experimental data and/or theoretical calculations such substances comply with the requirements of Article. 11 of Regulation (EU) No 10/.2011 paragraph 3, letters "a" and "b"; of Italian Ministerial Decree (D.M.) 21/03/1973.

The global migration limit, with the other restrictions (primary aromatic amines according to Regulation 10/2011/EU annex II point 1.2) and the substances above mentioned, respect the limits of the same legislation. In accordance with the statements received from our suppliers regarding the raw materials used in the current formulation of the above- mentioned hoses, the substances defined as "Biocides" (Regulation 528/2012/EU and subsequent additions) are not intentionally added during the production of the hoses.

Dual-use additives. In the hose there are the following substances regulated by Regulations (EC) N. 1333/2008 (food additives) and 1334/2008 (flavourings), and subsequent updates:

E 171 Titanium Dioxide;
E 470a Sodium, Potassium And Calcium Salts Of Fatty Acids;
E 570 Fatty Acids;

The declaration refers only to the suitability for contact with foodstuffs with the a.m. restrictions.

This declaration will be updated in the event of changes in formulation of the material or if the legislative references are updated so as to require a new check for compliance.

Kind regards,
AKBO Handelsmij B.V.

R.L.V. Platjouw