



Date of Declaration: 22/02/2023

Subject: European Plastic Regulation (EU) No 10/2011

To: Byggros Holding A/S

## DECLARATION OF COMPLIANCE

We hereby declare that our hoses given in Annex (A) 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.

### **In compliance with the following EU legislation;**

- Regulation 1935/2004/EC
- Regulation 2023/2006/EC (GMP)
- Regulation 10/2011/EC and sub amended

The materials and raw materials used comply with European Plastic Regulation (EU) No 10/2011; the following substances subject to limitation and/or specification have been used in products which are the listed at Annex (A).

Name of substance	SML
Terephthalic acid , bis(2-ethylhexyl ester) , FCM substance no : 798 , Ref No. 92200 Group restriction No : 32	60 mg/kg SML (T)
Soybean oil , epoxidised , FCM substance no : 532 , Ref No. 88640 Group restriction No : 32	60 mg/kg SML (T)
Calcium salt or fatty acid	No SLM but calcium salts or fatty acids to be considered as dual use

This declaration is valid for the product as described and delivered by us. The verification of compliance was performed based on the rules set out in Regulation (EU) No 10/2011; according to which the product complies with the legal requirements subject to adherence to the stated conditions for the contact with food. In case of deviating food contact conditions, it is up to the user to verify the suitability.

In particular it is emphasized that in the case of printed material, no contact is allowed between the printing ink and the food product.

### Test Conditions(specific migration)

Simulant A : ethanol at 10% in aqueous solution //Time and Temperature: 2 hours at 70°C (repeated use)

Simulant B: acetic acid at 3% in aqueous solution// Time and Temperature: 2 hours at 70°C (repeated use)

Simulant C: ethanol at 20% in aqueous solution //Time and Temperature: 2 hours at 70°C (repeated use)

Simulant D1: ethanol at 50% in aqueous solution// Time and Temperature: 2 hours at 70°C (repeated use)

*The simulants and test conditions were chosen according to Regulation 10/2011/UE (annex III tab. 1 and annex V tab.3) The test of global migration for the simulant is made in compliance with annex V tab 3 test OM3.*

The global migration limit, with the other restrictions (metals, 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 updated to Regulation 1245/2020/EU.

In accordance with the statements received from our suppliers regarding the raw materials used in the current formulation of the mentioned hoses, the substances defined as "Biocides" (Regulation 528/2012/EU and subsequent additions) are not intentionally added during the production of the hoses.

We confirm that during manufacturing of products specified in Annex (A) , we do not intentionally add into products any of the below mentioned substances and therefore are not expected to be present in below products. Phthalates : DEHP, DBP, BBP, DINP, DIDP, DEP, DCHP, DMEP, DMCHP, Di-benzyl phthalate. The residual content of vinyl chloride monomer on the product does not exceed 1mg/kg acc. to requirement of European Directive

The declaration refers only to the suitability for contact with foodstuffs with the limitations indicated above.

The hoses are only suitable for fluid conveyance. Avoid contact of food with the head and outer surface of hose. The hoses must be sterilized prior to use.

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

Best regards,

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**ANNEX A: Product Codes**

<b>ANNEX (A) ; List of products supplied to Costumer</b>		
<b>Description of Products</b>		<b>Food Simulant</b>
<b>Triavyl AL</b>	<b>All sizes</b>	Sim A-B-C
<b>Jotaflex Food</b>	<b>All sizes</b>	Sim A-B-C

*This information is partly based on our suppliers' information. Please accept that Polimer Kauçuk SAN. ve PAZ. A.Ş. does not regularly test for the absence of all substances. This Manufacturer's Declaration is only valid under the condition that we , the manufacturer , are correctly informed by our suppliers.*