

Declaration of Compliance

Identification of Supplier:

Company name	Ahlsell Danmark A/S
Address	Jydekrogen 2A, DK – 2625 Vallensbæk Denmark
E-mail	produktsikkerhed@ahlsell.dk
Website	www.ahlsell.dk
Is registered at The Danish Veterinary and Food Administration: http://www.findsmiley.dk/da-DK/Searching/DetailsView.htm?virk=10957106	

Conformity:

Ahlsell DK hereby declare that the products complies with the European regulations:	
(EC) No 1935/2004:	Materials and articles intended to come into contact with food.
(EU) No 10/2011:	Plastic materials and articles intended to come into contact with food.
(EC) No 2023/2006:	Good manufacturing practice for materials and articles intended to come into contact with food.
(DK) 681/2020:	Regulation 681/2020 for materials and articles intended to come into contact with food.

Products covered by this DoC:

Danish:	Armeret PVC slange 6x12mm (blå, gul, rød) 50m
English:	ADFLEX CRYSTAL RETEX ML
Please refer to the supplier DoC (next page) for area of application and technical information.	

Date:	Sign:
29.01.2025	
	Head of Product safety Dot Sør

San Vittore Olona, 11/12/2024

SUBJECT: COMPLIANCE DECLARATION FOR MATERIALS AND ARTICLES INTENDED FOR FOOD CONTACT

According to Regulation (EU) 2020/1245

1. With this document, we certify that the following product classes:

- **ADFLEX CRYSTALCLEAR Atox**
- **ADFLEX CRYSTAL RETEX SL**
- **ADFLEX CRYSTAL RETEX ML**
- **ADFLEX CRYSTAL RETEX HL**
- **SANIFLOW**

Produced by ADFlex Spa (Industrial Site – Busto Arsizio, Viale dell'industria 23, VA 21052 ITALY)

Are compliant with:

the main Regulations, in particular, the following:

- Regulation (EU) 10/2011 and subsequent amendments
- Regulation (EU) 2020/1245
- Directive 2002/72/EC, 2007/19/CE and subsequent amendments
- Regulation (EC) 1895/2005
- Regulation EC 2023/2006 (GMP)
- Regulation 1935/2004/EC

and the following Italian Regulations:

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

2. The above-mentioned articles are produced with the following food contact materials *:

- Inner layer of plasticized PVC (contact side)
- Polyester yarn reinforcement
- Outer layer of plasticized PVC.

*CRYSTALCLEAR only has the inner layer of plasticized PVC.

ADFlex S.p.A.

Sede Legale – Via C. Correnti 11, San Vittore Olona 20028 (MI) P.IVA IT08433990150 Codice SDI BA6ET11

Sede Operativa – Viale dell'Industria 23, Busto Arsizio 21052 (VA)

Tel: +39 0331 517386 – Mail: info@adflexgroup.eu

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

Substance Name	Reference Number	CAS Number	Limit Type and Value	(restriction number and group)	Restrictions and/or specifications
Acid terephthalic, bis(2-ethylhexyl) ester	92200	6422-86-2	LMS= 60mg/Kg	(32)	
Epoxidized soybean oil	88460	008013-07-8	LMS= 60 mg/Kg 30 mg/Kg*	-	* for PVC gaskets used to seal glass jars containing infant and follow-on formulae as defined by Directive 2006/141/EC or cereal-based foods and baby foods as defined by Directive 2006/125/EC, the LMS is reduced to 30mg/kg
Zinc salts (including double salts and acid salts) of authorized acids, phenols, or alcohols (*)	-	-	LMS = 5mg/kg expressed as Zinc	-	-

Table 1 Substances subject to restriction

(*) In Annex to Regulation (EU) No. 2016/1416, point 2, letter a), the specific migration limit changes from 25mg/kg to 5mg/kg for zinc, and the limit of 1mg/kg for aluminum is introduced. Based on Article 3, these provisions apply from September 14, 2018.

4. According to our knowledge, we can confirm that certain Dual Use substances are present in the product as described in Table 2 and that the product does not contain Non-Intentionally Added Substances (NIAS).

Name	E number
Products from the thermic reaction between mono and diglycerides fatty acid of the oxidized soy bean oil	E479b

Table 2 Substances Dual Use

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5. We certify that:

The mentioned article is compliant with the global migration limits and specific migration limits under the following test conditions:

- Simulant A: 10% v/v AQUEOUS SOLUTION OF ETHANOL (for aqueous foods).
Test duration and temperature: 10 days at 40°C.

- Simulant B: 3% v/v AQUEOUS SOLUTION OF ACETIC ACID (for acidic foods).
Test duration and temperature: 10 days at 40°C.

- Simulant C: 20% v/v AQUEOUS SOLUTION OF ETHANOL (for aqueous foods).
Test duration and temperature: 10 days at 40°C.

The article complies with the global migration limits and other specific restrictions that the monomers and/or additives contained in it may be subject to under the aforementioned conditions of use. The stated compliance is supported by analytical tests conducted in accordance with DM 21/03/1973 and Articles 17 and 18 of Regulation (EU) 10/2011, together with Annex V of the same regulation, or based on calculations considering the percentage of substances subject to migration limits under the test conditions. The calculations are performed assuming that 1 kg of food comes into contact with 6 dm² of the article. Please note that the Global Migration Limit is 60 mg/kg of food (ppm), alternatively expressed as 10 mg/dm² (if the certificate reports a value expressed in mg/kg, it can be converted to mg/dm² by dividing the value by a factor of 6), and we emphasize that the analytical tolerance is set between 10% and 20% (12 mg/kg or 2 mg/dm²).

6. We consider it the responsibility of the user to correctly use the product according to the conditions and types of food as described in Regulation (EU) 10/2011.
7. This declaration complies with Article 16 of Regulation 1935/2004/EC.
8. The industrial or commercial use of the article subject to this declaration is subject to the evaluation of its compliance with the actual regulations and technological suitability for the declared end use.
9. This declaration is valid from the date stated above and will be renewed if substantial changes in the production process (finished product/raw materials) lead to modifications of the necessary characteristics, or if new amendments to the regulations mentioned in Point 1 require new checks to verify the suitability of the article in question.
10. We also inform that all supporting documents are available to the competent authorities in accordance with Article 16, Paragraph 1 of Regulation 1935/2004/EC.

Best Regards,

ADFlex SpA
Via C. Correnti 11
20028 SAN VITTORE OLONA (MI)
C.F. & P.IVA IT 08433990150



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