

DECLARATION OF CONFORMITY

PRODUCT:	ESPIRO P.U.
CODE:	341000XX

REV:	1
DATE:	06/09/2022

Hereby, Espiroflex states that the products with the code referenced above:

This product is made of the following materials listed, a PVC-U spiral coated with TPU (Thermoplastic Polyurethane).

This products are produced according to the following community legislations:

Regulation (CE) n° 1935/2004
 Regulation (CE) n° 1895/2005
 Regulation (CE) n° 2023/2006
 Regulation (UE) n° 10/2011 and subsequent updates

The product passes the test of the GML (global migration limit) according to the current normative, UNE-EN 1186-1 and UNE-EN 1186-8. Test number: AT-1445/19, made by AIMPLAS.

PROPERTY	SIMULANT	REQUIREMENT [mg/dm ²]	AVERAGE VALUE [mg/dm ²]	RESULT
Global migration	B	< 10	6,5	OK
Global migration	C	< 10	< 0,6	OK

It is according to the organoleptics requirements, established in the (CE) 1935/2004 regulation.

Restricted substances and components:

The product has the following restricted substances included in the annexes I and II of the (UE) 10/2011 regulation, from the current law. These tests have carried out by Aimplas and the results are represented in the AT-0187/19 inform number.

Chemical Name	N° MCA	N° de Ref.	N° CAS	Restriction LME [mg/kg]
Substance A*	Confidential	Confidential	Confidential	0,6
Substance B*	Confidential	Confidential	Confidential	5
Substance C*	Confidential	Confidential	Confidential	6
Substance D*	Confidential	Confidential	Confidential	3
Substance E*	Confidential	Confidential	Confidential	60
Substance F*	Confidential	Confidential	Confidential	1
Substance G*	Confidential	Confidential	Confidential	ND (LD=0,01)
Substance H*	Confidential	Confidential	Confidential	45

(*) These compounds are submitted under a confidentiality agreement, between our supplier and the external laboratory.



ESPIROFLEX

FABRICA DE TUBERIA FLEXIBLE

SML test conditions:

1) Restricted substances.

Simulant B, C, and E; 2 hours at 70 °C.

The specific migration will be checked based on 100% migration of the results of the residual content. If this result is lower than the SML, the SML can never be reached by migration.

Terms of use:

This product can be used for foods that have a hydrophilic character and are able to extract hydrophilic substances.

The simulant B, will be used with foods with a pH lower than 4,5. The simulant C will be used with alcoholic foods with an alcoholic graduation lower than 20 % degree and with foods with a significant amount of organic ingredients, that render the food more lipophilic.

This product can be used in repeated use conditions for a maximum of 2 hours at 70 °C.

The ratio between the food contact surface used to determine the conformity of the sample has been 7,1 dm²/kg and 8,1 dm²/kg to the global migration and 6 dm²/kg to the specific migrations.

The simulants and test conditions have been selected in accordance with Regulation (EU) 10/2011 Annex III Table 1 and Annex V Table I and II. It is the responsibility of the final customer to sterilize this product before use.

Materials Manager