

# Confirmation

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Food safe of bioFila® silk

## European Union:

We confirm that the material is conform with

**EG 1935/2004** of the European Parliament and Council form Oct 27th 2004 about material and parts, which can have a contact with food.

and

the german law „**Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)**“ version from July, 24th 2009 and the last version of part 5 of the law from Dec 9th 2010 §§30 and 31.

and

**EU 10/2011** of the european council about material and parts made out of plastic and are assigned for the contact with food in the version from Jan, 14th 2011.

There are the following specific restriction:

- 1,4-Butandiol:	SML = 5mg/kg
- Terephthal acid:	SML = 7,5mg/kg
- Hexmethylenendiisocyanat:	SML(T) = 1mg/kg, in the part, calculated as Isocyanat-group (NCO)

SML: specific migration value of substance;

SML(T): migration value of a group of substances, with group-restrictions

**USA:**

The material is confirm with the requests of the U.S. Food and Drug Administration (FDA):

21 CFR § 177.1660 21 CFR § 182  
21 CFR § 184  
21 CFR § 186

21 CFR § 175.105 “Adhesives”  
21 CFR § 175.300 “Resinous and polymeric coatings”  
21 CFR § 176.170 “Components of paper and paperboard in contact with aqueous and fatty foods”  
21 CFR § 176.200 “Defoaming agents used in coatings”

21 CFR § 177.2600 “Rubber articles intended for repeated use”  
21 CFR § 178.2010 “Antioxidants and/or stabilizers for polymers”.

Under use of the FDA conditions of use C to G (see FDA 21 CFR 176,170(c), table 2)

**Attention:**

A sound processing of the material is pre-condition for the suitability of use as food-safe material. In every single case the manufacture of the part has to prove the suitability of use.

For any questions don't hesitate to contact us.

best regards

twoBEars GbR

This is an computer-produced document and does not required a signature.

The information above are the results of product test and are our current level of awareness and the status of legislation at issue date. The confirmation expires after 12 months or modification of the relevant laws. If required a new confirmation has to be ordered. Trade mark rights or law has to be respected by the recipient of our products