



Thursday, 08.01.2026

REGULATIONS FOR USE IN FOOD AND SKIN CONTACT

Trade Name:

- **Filaflex 60A transparent, white, nude and black colors.**
- **Filaflex 70A transparent, white, nude, navy blue and black colors.**
- **Filaflex 82A transparent, white, nude, blue, blue food grade, brown, gold, green, grey, orange and black colors.**
- **Filaflex 95A transparent, white, nude, blue, blue food grade, green and black colors.**

Here we give you information concerning basic regulations regarding materials intended for use in contact with foodstuffs and skin.

The used raw materials and additives comply with the consumer article regulation (and/or correspondences) into the European plastic regulation EU 10/2011 as well as the transition periods and changes of this guideline valid at the time of the distribution of this declaration (up to (EU) 2017/752). This product has been manufactured in accord with regulation over good manufacturing practice for materials and articles intended to come into contact with food (GMP) 2023/2006/EC.

The composition of the products complies with the requirements of FDA Regulation 21 CFR 177.2600 "Rubber Articles Intended for Repeated Use". Above mentioned products do not contain dual use additives.

According to our experience it is most likely that finished products in above mentioned Filaflex types will fulfil requirements for irritation, sensitisation and cytotoxicity, assuming the materials are correctly processed and providing no unacceptable additives are included. This must however be confirmed by an authorized laboratory analysing risk-based approach to biocompatibility of the final product under conditions of use, according to the requirements of ISO 10993 "Biological assessment application and body contact time".

General requirements for Food Contact and Skin Contact

In order to avoid material degradation it is necessary to ensure that the moisture content of the granulate at the point of processing is less than 0.02%. The maximum service temperature of material produced from Filaflex should not exceed 40o.



Compliance with the provisions of Regulation (EC) No 1935/2004 especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any given limitations, must be ensured by the person who introduces the articles into circulation.

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The information indicated above corresponds to our present knowledge and refers to the state of the legislation at the date of issue. THIS STATEMENT EXPIRES 18 MONTHS AFTER THE DATE OF ISSUE or in case of regulatory changes before such date. It is the responsibility of the recipients of our products to ensure that any other existing legislation is observed. The statement is generated electronically and is valid without signature. The product information is exclusively for our customers. It is not intended for publication either in printed or electronic form (e.g. via Internet) by others. Thus, neither partial nor full publication is allowed without written permission.