

September 05, 2022

SPECTRUM GROUP

Confirmation

ELIX ABS-3D FC 000000

- **Application:** 3D printed part for food contact application

EU Food Contact Regulation

Materials used in food contact applications are regulated in Europe by the following regulations and directives:

- | | |
|------------------------------------|--|
| Regulation (EC) 1935/2004 | on materials and articles intended to come into contact with food |
| Commission Regulation (EU) 10/2011 | on plastic materials and articles intended to come into contact with food, and its amendments including Commission Regulation (EU) 2020/1245 |

Compositional Requirements

The above-mentioned European regulation and directives define the following compositional requirements:

- Authorized substances
- General requirements on substances
- Specific requirements on substances
- General restrictions on plastics materials and articles
- Specific migration limits
- Overall migration limit of < 10 mg of total constituents released per dm² of food contact surface
- Overall migration limit of < 60 mg of total constituents released of 1 kg of food simulant (for applications used by infants and young children)

Compliance of ELIX

The above mentioned ELIX products:

- comply with relevant requirements set out in Article 3 of Regulation 1935/2004/EC under intended and foreseeable use
- comply with the labelling requirements set out in Article 15 of Regulation 1935/2004/EC
- comply with the traceability requirements set out in Article 17 of Regulation 1935/2004/EC
- are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006
- comply with compositional and declaration requirements set out in Chapter II, III and IV of Regulation (EU) No 10/2011 and its amendments.

European Regulation

Authorized substances

The above-mentioned materials are in compliance with the requirements and specifications of Regulation (EC) 1935/2004 (declaration of conformity).

Regarding its monomer and additive composition, the products also comply with Commission Regulation (EU) No. 10/2011 and its amendments. All monomers and additives used in the above-mentioned materials are listed in Annex 1.

Specific migration limits

According to Commission Regulation (EU) No.10/2011 and its amendments, for the monomers and additives in the above-mentioned materials the following limits must be observed:

<i>Butadiene</i>	max. residual content in the article: < 1 mg/kg of the polymer or as an alternative specific migration limit: not detectable (detection limit < 0,01 mg/kg related to foodstuff)
<i>Acrylonitrile</i>	specific migration limit: not detectable (detection limit < 0,01 mg/kg related to foodstuff)
<i>Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate</i>	specific migration limit: < 6 mg/kg of foodstuff

It could be expected that the above material shall fulfil the requirements for food contact material set in regulations 10/2011/EU and therefore may be suitable for single and repeated short term use (repeated use articles) of hydrophilic and lipophilic food without heating.

ELIX Polymers has **not** tested all above mentioned specific migrations limits (SML's) on the aforementioned products.

The compliance with specific migrations limits on the finished article is the responsibility of the business operator and depends on the use of the material or article:

- type or types of food with which it is intended to be put in contact
- time and temperature of treatment and storage in contact with the food
- ratio of food contact surface area to volume used to establish the compliance of the material or article.

German Regulation

The BfR (Bundesinstitut für Risikobewertung / Federal Institute for Risk Assessment) has published "Recommendations on the health assessment of plastics and other high polymers". The BfR Recommendations on Food Contact Materials are based on European law and its transposition into national law.

For natural ABS materials the following BfR recommendation apply:

Recommendation VI: Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers

With respect to its volatile components, additives and further constituents the above-mentioned materials shall comply with this BfR Recommendation.

It is the responsibility of our customers to determine if articles made out of above-mentioned materials are suitable for the intended use and comply with all applicable regulations and requirements.

The above-mentioned confirmation only applies to granules delivered by ELIX Polymers S.L.



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