



Thursday, 19.03.2020

REGULATIONS FOR USE IN FOOD AND SKIN CONTACT

Trade Name:

- **PLA white and black colors.**

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

The used polylactic acid compound and additives comply with the consumer article regulation (and/or correspondences) into the European plastic regulation EU 10/2011 as well a specific measure of Regulation EC 1935/2004 that repeals Commission Directive 2002/72/EC and all its following updatings (2004/19/CE - 2005/79/CE - 2007/19/CE – 2008/39/CE – REGULATION N° 975/2009).

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.

We furthermore would like to bring your attention to Directives 97/48 / CE and 85/572 / CEE, which have also been updated by European Reg. 10/2011, about the simulates to be used and the introduction of the coefficient of reduction for fatty substances (FRF).In this sense we would like to bring your attention to the fact that some components of the formulation are subject to restrictions and can be used for contact with foodstuffs which use the simulates A-B-C-D1-D2-E.



According to our experience it is most likely that finished products in above mentioned PLA 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 40°.

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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