

Declaration of Compliance
according to Regulation (EU) 10/2011 Annex IV

- Bio-Flex[®] V 135001 -

Manufacturer:

FKuR Kunststoff GmbH
Siemensring79

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Bio-Flex V 135001 is in compliance with the following legal requirements (in each case including all amendments in their relevant versions up to the time of the issue of this statement):

European Union (EU)

General

- EU-Framework Regulation on materials and articles intended for food contact: (EC) No **1935/2004** of 27 October 2004
- **German Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)** of 07 September 2005
- EU-Regulation on good manufacturing practice for materials and articles intended to come into contact with food: (EC) No. **2023/2006** of 22 December 2006

Raw Materials

In the manufacture of **Bio-Flex V 135001** only substances are used listed in Annex I of Regulation **EU No 10/2011** of 14. January 2011.

Conditions of use / Compliance with threshold values

Specification of the intended use or limitations

Bio-Flex V 135001 is suitable for packaging in dry, aqueous, acetic and fatty foodstuffs at any condition of time at room temperature and below.

Overall Migration

Overall Migration was carried on comparable products under following contact conditions (EC-Directives **85/572/EWG** and **82/711/EWG** amended by **93/08/EWG** and **97/48/EG**):

Simulant	Contact Time [d]	Temperature [°C]
Iso-octane	2	20
3% acetic acid	10	40
50% ethanol	10	40
95% ethanol	10	40

Overall Migration is well below the limit of 10 mg/dm² without application of permitted reduction factors for the above stated conditions of use.

Limitations and/or specifications

For the following substances used in the production of **Bio-Flex V 135001** limitations and/or specifications have been stipulated in Regulation **EU No 10/2011**:

Substance name	FCM substance No	SML [mg/kg]	SML (T) [mg/kg] (Group restriction No)	Restrictions and specifications
-				

Dual Use Additives

In the manufacture of **Bio-Flex V 135001** the following substances are used which are subject to a restriction in food.

Substance name	FCM substance No / CAS No	E-number
lactic acid	99 / 50-21-5	E 270

Summary

By observing the above regulations, the duty of care regarding the compliance of the product with legislation governing food contact applications has been fulfilled. It is the responsibility of the user to verify its suitability for his own intended food application. In particular according to Regulation (EU) 10/2011 verification of compliance with the migration limits is within the responsibility of the manufacturer of the finished plastic food contact material or article. No liability for losses arising from the inadequate suitability of the product for the particular content being used is accepted.

The declaration is based on information made available by FKUR Kunststoff GmbH and their suppliers to fcc-foodcontactconsulting gmbh by date.

The content of this certificate is strictly confidential and should not be passed on to third parties. However in case your customer requires this information in order to assess compliance and measuring migration as required by law, you are entitled to pass them on to the customer or a neutral institute, under the strict obligation that the information is treated strictly confidential.

This declaration shall continue in effect for 1 year from its effective date unless it is modified before. The validity also ends upon change of the corresponding legislations. If further information is required please do not hesitate to contact us.

Date of Declaration: 22.04.2014



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