BIOTEC®
BIOPLASTICS FOR A BETTER LIFE

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April 15th, 2016

Declaration of Conformity with the Requirements of Food Contact Legislation

BIOPLAST® 300

BIOPLAST 300 resp. the raw materials used for BIOPLAST 300 comply with the following legal requirements or recommendations:

1. Generally:

   - EU-Framework Regulation on materials and articles intended for food contact No 1935/2004
   - Additionally for German customers: LMBG §§ 30 und 31

2. Raw Materials:

   EU-Directives:

   - EU 10/2011 and amendments

   German regulations:

   - Commodities Regulation of 10.04.1992 and amendments
   - BfR-Recommendations

   Non-EU-regulations:

   - FDA

3. Conditions of Use / Compliance with Threshold Values

a) Specification of the conditions of use by the customer: Kind of packed food, time of contact, contact temperature

b) Specification of tested conditions of use with maximum test requirements by the customer: Longest possible time of contact, highest possible contact temperature (without exceeding Overall Migration Limit, OML, and Specific Migration Limits, SML)

OML: The observance of the global migration values according to the requirements of Directive EU 10/2011 produces values below the admitted threshold values (for the above mentioned conditions of use).

SML/QM: Substances with SML- or QM-values are used. The following restrictions have to be ensured:

- Hexamethylenediisocyanate: QM(T) = 1 mg/kg, calculated as NCO; SML(T) = ND, calculated as NCO
- 1,4-Butanediol: SML(T) = 5 mg/kg
- Terephthalic acid: SML(T) = 7.5 mg/kg
- Tetrahydrofurane: SML = 0.6 mg/kg

QM(T): Maximum permitted quantity of the residual substance in the material or article, expressed as total of moiety/substance(s) indicated

SML(T): Specific migration limit in food or food simulant, expressed as total of moiety/substance(s) indicated

Depending on the processing conditions, tetrahydrofurane (THF) and 1,4-butanediol may be formed, leading to residual contents of these substances in the finished article. Therefore, the specific migration limits of THF (SML = 0.6 mg/kg) and 1,4-butanediol (SML(T) = 5 mg/kg) must be ensured by the person, who introduces the articles into commerce.

4. Dual Use Additives

Following material, which can be used as additive for food and food packaging (dual use), is present in BIOPLAST 300:

- E 491: Sorbitanemonostearate

5. Further Declarations of Conformity

   a) Heavy metals, according to EU-Directive 94/62/EC on Packaging and Packaging Waste

   b) Plasticizers: - Phthalates
   - BADGE, NOGE, BFDGE, according to EC No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

6. Conclusion

   In terms of EU-Framework Directive (EC) No 1935/2004 and §§ 30 and 31 LMBG, published in the Bundesgesetzblatt (Federal Law Gazette) Nr. 63 of 17.09.1997, there are no objections against the use of BIOPLAST 300 for the manufacture of articles intended for food contact.

This confirmation applies to the resin delivered by BIOTEC. The verification if the packaging or packaging film is suitable for the intended purpose of use and the filled good is subject to the user, i.e. the packaging manufacturer is not responsible for quality modifications of the packed food due to chemical reactions with the packaging material or its components. It is expressly pointed out, that any contact between printing ink and food must be avoided.

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