Fraunhofer Institut
Verfahrenstechnik
und Verpackung

Certificate

Food regulatory assessment of laser sintered polyamide PA 2200

Client: EOS GmbH, 82152 Krailing, Germany

Order: PA/4152/03 and PA/4185/03

The compositional compliance with the EU Plastics Directive 2002/72/EC is stated by the manufacturer of the raw polymer used for the laser sintering process with the restriction for use with non-alcoholic foodstuffs only.

The overall migration and the specific migration of laurolactam and the used antioxidant into 3 % acetic acid, 10 % ethanol and olive oil at the contact conditions 24 h at 20 °C was in compliance with the overall migration limit 10 mg/dm² contact surface of the article and with the respective specific migration limits according to EU-Plastic Directive 2002/72/EC (Fraunhofer IVV test reports PA/4152/03 dated 30.6. and 3.7.2003). The results obtained from testing sticks are valid for articles of all geometrical forms and thicknesses.

Additionally the effect of the laser sintering process on migratable substances was investigated (Fraunhofer IVV test report PA/4185/03 dated 4.7.2003). The results show that the sintering process does not produce any detectable additional substances compared to the raw polymer. Volatile substances are reduced during the sintering process.

From this it can be concluded that articles produced from PA 2200 by the EOS laser sintering process are in compliance with the EU Plastics Directive 2002/72/EC for the use with all types of foods except high alcoholic foodstuffs at contact conditions up to 24 h at 20 °C.

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Freising, 17.7.2003

Dr. Roland Franz
(Head of migration laboratory)

Dr. Angela Störmer
(Dep. head of migration laboratory)

BIOCOMPATIBILITY

Certificate

Test Item:	PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)
Supplier:	EOS GmbH Electro Optical Systems Robert-Stirling-Ring 1, 82152 Krailling, Germany
Studies performed:	The following studies were performed in order to determine the biocompatiblity of the product PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System), Batch No. 919389 according to ISO 10993-1:

CYTOTOXICITY (BSL Study No. 094861)

SENSITISATION [1] (BSL Study No. 094864)

INTRACUTANEOUS REACTIVITY (BSL Study No. 094863)

Results: **The product did pass the requirements in the studies performed. Therefore, the biocompatiblity of the test material was proved.**

1) LLNA (Local Lymph Node Assay)

BSL BIOSERVICE Scientific Laboratories GmbH Munich

Behringstraße 6

82152 Planegg

Germany

Dr. Ingrid Haist
Biological Safety Testing
Date: 19 March 2010

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ZLG-P-986.96.01

BIOSERVICE
SCIENTIFIC LABORATORIES GmbH

BIOCOMPATIBILITY

CERTIFICATE

Testmaterial: **PA 2200**

Supplier: EOS GmbH
Pasinger Strasse 2, D-82152 Planegg

Studies performed: The following studies were performed in order to determine the biocompatiblity of the product PA 2200 according to ISO 10993-1:

CYTOTOXICITY

SENSITISATION, polar extract

SENSITISATION, non-polar extract

INTRACUTANEOUS REACTIVITY

Results: **The product did not show any adverse effects in the studies performed. Therefore, the biocompatiblity of the test material was proved.**

BSL BIOSERVICE Scientific Laboratories GmbH Munich

Behringstraße 6

D-82152 Planegg

Dr. Achim Albrecht

Biological Safety Testing

Date: April 10, 2001

BIOSERVICE Scientific Laboratories GmbH GLP EN 45001