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.

Fraunhofer Institut
Verfahrenstechnik
und Verpackung

Freising, 17.7.2003

Dr. Roland Franz
(Head of migration laboratory)

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

F D A / TO WHOM IT MAY CONCERN

Food suitability

According to the Food and Drug Administration (FDA), 21 CFR, §177.1500 (Nylon Resins), the single components of PA 2221 are currently licensed in the U.S.. The license excludes contact with alcohol-containing foods and beverages and is restricted to §177.1500, (b) 9.

Product	PA 2221
Company	EOS GmbH
Address	Robert-Stirling-Ring 1 82152 Krailling / München Germany
Phone	+49 (0)89 / 893 36-0
Fax	+49 (0)89 / 893 36-285

Date 05 October 2011

Authorized signature

Authorized name Johann Oberhofer – Chief Operating Officer

EOS GmbH – Electro Optical Systems
Robert-Stirling-Ring 1
D-82152 Krailling / München
Telephone: +49 (0)89 / 893 36-0
Telefax: +49 (0)89 / 893 36-285
Internet: www.eos.info

PA 2200
Regulatory Information

Regulatory Information on PA 2200

Table of Content

To whom it may concern

Dear Sir or Madam,
Please note that some of the information provided herein is based on information from raw material suppliers. For required certifications on raw material as well as sintered material e.g. biocompatibility tests we work together with accredited test laboratories / houses.
Relevant information regarding product stewardship and occupational safety and health can be obtained from the Safety Data Sheet. For material information please refer to our material datacenter, available at our website http://eos.materialdatacenter.com/eo/de.

Biocompatibility

All biocompatibility certificates have been checked for validity by an accredited test laboratory in October 2012. The conclusions and test results are still valid.

1. Biocompatibility - Parts made of new powder

In vitro Cytotoxicity Assay: Cell Growth Analysis via BCA-Staining with an Extract of PA 2200 (acc. to ISO 10993-1: 1997, "Evaluation and testing", ISO 10993-5: 1999, "Tests for in vitro cytotoxicity", ISO l0993-12: 1996, "Sample preparation and reference materials")
This is to confirm that the cytotoxic effects of PA 2200 were analyzed. Under the given conditions no leachable materials were released in cytotoxic concentrations from the test item.

Biocompatibility - Test for Sensitization (Guinea Pig Maximisation Test, non-polar extract) (acc. to ISO 10993-1: 1997, "Evaluation and testing", DIN EN ISO 10993-10:1995, "Tests for irritation and sensitization", ISO 10993-12:1996 "Sample preparation and reference materials")
This is to confirm that the sensitization rate after application of the non-polar extract of the test item was 0 %. Under the test conditions the test item showed no signs of allergenic potency. PA 2200 is considered to have no sensitizing properties.

Biocompatibility - Test for Sensitization (Guinea Pig Maximisation Test, polar extract) (acc. to ISO 10993-1: 1997, "Evaluation and testing", DIN EN ISO 10993-10:1995, "Tests for irritation and sensitization", ISO 10993-12:1996 "Sample preparation and reference materials")
This is to confirm that the sensitization rate after application of the polar extract of the test item was 0%. Under the test conditions described the test item showed no signs of allergenic potency. PA 2200 is considered to have no sensitizing properties.

Biocompatibility - Irritation Test (Intracutaneous Reactivity) (acc. to ISO 10993-1: 1997, "Evaluation and testing", DIN EN ISO 10993-10:1995, "Tests for irritation and sensitization", ISO 10993-12:1996 "Sample preparation and reference materials")
This is to confirm that the intracutaneous injection of the polar and non-polar extract of the test item to rabbits caused no signs of irritation / corrosion compared to the injection sites of the reagent control.

2. Biocompatibility - Parts made of recycled powder

Biocompatibility - In vitro Cytotoxicity Assay: Cell Growth Analysis via BCA-Staining with an Extract of PA 2200 reused powder (50% virgin + 50% recycled powder from EOSINT P System) (acc. to ISO 10993-1: 2009, "Evaluation and testing within a risk management process", ISO 10993-5: 2009, "Tests for in vitro cytotoxicity", ISO l0993-12: 2007, "Sample preparation and reference materials")
This is to confirm that the cytotoxic effects of PA 2200 reused powder (50% virgin + 50% recycled powder from EOSINT P System) were analyzed. Under the given conditions no leachable materials were released in cytotoxic concentrations from the test item.

Biocompatibility - Irritation Test (Intracutaneous Reactivity) with PA 2200 reused powder (50% virgin + 50% recycled powder from EOSINT P System) (acc. to ISO 10993-1: 2009, "Evaluation and testing within a risk management process", DIN EN ISO 10993-10:2007 (ISO 10993-10:2002 + Amendment 1:2006) "Tests for irritation and delayed-type hypersensitivity", ISO 10993-12:2007 "Sample preparation and reference materials")
This is to confirm that the intracutaneous injection of the polar extract of the test item to rabbits caused no signs of irritation compared to the injection sites of the reagent control. Very slight signs of irritation were found for the nonpolar extract as well as the nonpolar reagent control. The Primary Irritation Index (PII) for the nonpolar test item extract and the nonpolar reagent control was 0 (control corrected).

Biocompatibility - Test for Sensitization (Local Lymph Node Assay - LLNA) with PA 2200 reused powder (50% virgin + 50% recycled powder from EOSINT P System) (acc. to ISO 10993-1: 2009, "Evaluation and testing within a risk management process", DIN EN ISO 10993-10:2007 (ISO 10993-10:2002 + Amendment 1:2006) "Tests for irritation and delayed-type hypersensitivity", ISO 10993-12:2007 "Sample preparation and reference materials")
This is to confirm that under the conditions of the study it can be stated that the test item PA 2200 reused powder causes no reactions identified as sensitization, as the stimulation index was below 3.0 for each concentration tested.

3. USP (United States Pharmacopoeia) Biological Test

The purpose of the study is to determine the biological response of animals to direct and indirect contact to polymers to assess their suitability as components of medical devices. In this test system materials and semi-products are tested. There are 6 plastic classes defined which are based on responses to a series of tests for which extracts, materials, and routes of administration are specified. In Plastic class VI, four extraction vehicles are used for extracting a wide range of possible leachables for the Systemic Injection Test and the Intracutaneous Test, and laser sintered pins are used for the Implantation Test.

USP Classification of Plastics - Plastic Class VI - 121 °C (This study followed the procedures indicated by the following internationally accepted guidelines and recommendations: USP "Biological Reactivity Test, in vivo - Classification of Plastics)

This is to confirm that in the Systemic Injection Test no significant clinical signs were observed. The average score in the Intracutaneous Reactivity Test was 0. In the Implantation Test no compound-related tissue reactions were found. Considering the reported data the test item PA 2200 powder meets the requirements of USP Plastic Class VI.

4. DIRECTIVE 2002/72/EC Plastic Materials and Articles intended to come into Contact with Foodstuffs

The overall migration at the contact conditions 24 h at 20 °C was in compliance with the overall migration limit 10 mg/dm^2 contact surface of the article and with the respective specific migration limits according to EU-Plastic Directive 2002/72/EC. 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. 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.

5. Sulphur concentrations

This is to confirm that PA 2200 is made from monomers of technical purity. In addition we confirm that we don't use for the manufacturing of PA 2200 intentionally substances based on sulphur. Based on these conditions the occurrence of those substances can be excluded except negligible amounts on the level of natural / technical impurities.

6. Halogen concentrations

This is to confirm that PA 2200 is produced from monomers of technical purity. In addition we confirm that for the manufacture of PA 2200 substances based on halogens aren't used. Based on these conditions the occurrence of those substances can be excluded except negligible amounts on the level of natural / technical impurities.

7. DRC (Democratic Republic of Congo) conflict free minerals (Section 1502 of U.S. Dodd Frank Act)

This is to confirm that for the manufacture of PA 2200 cassiterite, columbite-tantalite, gold, wolframite or their derivates originated from the Democratic Republic of Congo or adjoining countries defined as Conflict Minerals is not used. Based on these conditions the occurrence of those substances can be excluded.

8. Directive 2005/84/EC relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles)

This is to confirm that we do not use intentionally di(2-ethyl hexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), di-isononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DNOP) mentioned in the EU directive 2005/84/EC) in our recipe to produce PA 2200.

PA 2200 is made of monomers of technical purity not formulated with any phthalate plasticizers. Based on this the occurrence of the above listed phthalates mentioned in the directive 2005/84/EC can be excluded, except negligible amounts on the level of natural / technical impurities.

9. Directive 2011/65/EU on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

This is to confirm that substances as mentioned in the following restricted by Directive 2011/65/EU (RoHS) explicitly are not intentionally used during the manufacturing process of PA 2200:

- Lead and its compounds
- Mercury and its compounds
- Cadmium and its compounds
- Chromium (VI) compounds
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ether (PBDE)

PA 2200 is made of raw materials of technical purity. Consequently, to our best knowledge and based on the aforesaid, the occurrence of those substances restricted by Directive 2011/65/EU (RoHS) can be excluded, except negligible amounts on the level of natural / technical impurities.
Please notice that our PA 2200 is not routinely analyzed for those substances listed above.

The official Statement of Compliance can be requested at the email address SAFETY_DATASHEET_RESPONSIBLE@eos.info.

10. Natural Rubber Latex

This is to confirm that we do not use intentionally natural rubber latex (as defined in US 21 CFR 801.437(b)) to produce PA 2200.
PA 2200 is made of raw materials of technical purity. Based on this the occurrence of natural rubber latex (as defined in US 21 CFR 801.437(b)) can be excluded, except negligible amounts on the level of natural / technical impurities.

11. PVC [Poly(vinyl chloride)]

This is to confirm that we do not use intentionally PVC [Poly(vinyl chloride)] to produce or formulate PA 2200.
PA 2200 is made of raw materials of technical purity. Based on this the occurrence of PVC [Poly(vinyl chloride)] can be excluded, except negligible amounts on the level of natural / technical impurities.

12. Halogenated Hydrocarbons (HOC)

This is to confirm that we do not use intentionally halogenated hydrocarbons (HOC) in our recipes to produce PA 2200.
PA 2200 is made of raw materials of technical purity. Based on this the occurrence of halogenated hydrocarbons (HOC) can be excluded, except negligible amounts on the level of natural / technical impurities.

13. Persistent Organic Pollutants (POPs)

This is to confirm that PA 2200 is made of raw materials of technical purity. Based on this the occurrence of persistent organic pollutants mentioned in the Regulation (EC) No 850/2004 can be excluded, except negligible amounts on the level of natural / technical impurities:

Substance	CAS-No.
Aldrin	309-00-2
Chlordane	57-74-9
Dieldrin	60-57-1
Endrin	72-20-8
Heptachlor	76-44-8
Hexachlorobenzene	118-74-1
Mirex	2385-85-5
Toxaphene	8001-35-2
Polychlorinated Biphenyls (PCB)	1336-36-3 and others
DDT (1,1,1-trichloro-2,2-bis(4-chlorophenyl) ethane)	50-29-3
Chlordecone	143-50-0
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDDI PCDF)	
Alpha, beta- and gamma- HCH	58-89-9, 319-84-6, 319-85-7
Hexabromebiphenyl	36355-01-8
Polychlorinated biphenyls (PCB)	
Polycyclic aromatic hydrocarbons (PAHs)	

Table 1: Persistent Organic Pollutants (POPs)

14. California Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1986

This is to confirm that none of the ingredients is listed (see MSDS chapter 15).

15. Substances of Animal, Vegetable, and GMO Origin

This is to confirm that PA 2200 is not manufactured using intentionally any products of animal, marine, dairy, grape, vegetable, and / or GMO (Genetically Modified Organisms) origin. PA 2200 is made of raw materials of technical purity. Based on this the occurrence of substances of animal, marine, dairy, grape, vegetable, and / or GMO (Genetically Modified Organisms) origin can be excluded, except negligible amounts on the level of natural / technical impurities.

16. REACH (pre)-registration - REGULATION (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

This is to confirm that PA 2200 fully complies with the requirements of the European Chemicals Regulation (REACH).

The official Statement of Compliance can be requested at the email address ORDER_PROCESSING@eos.info.

17. Substances of Very High Concern (SVHC) - REGULATION (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

This is to confirm that based on our present best knowledge the occurence of SVHC (Substances of Very High Concern) published in the "Candidate List" by ECHA under http://echa.europa.eu/chem_data/candidate_list_en.asp can be excluded, except for negligible quantities on the level of technical impurities below 0.1% (w/w).

18. Global Automotive Declarable Substance List, Edition 2013 (GADSL), revised March 01, 2013

This is to confirm that we do not use intentionally the below listed substances mentioned in the GADSL (Global Automotive Declarable Substance List) in our receipts to produce or formulate PA

2200. The official reference for the GADSL, Edition 2013 can be requested at https://web.emmg.ford.com/gmir/cgi-bin/rsms_confirmation.cgi.

In addition we confirm that the following substances are not intentionally used and / or added during the manufacturing process of PA 2200. Therefore the occurrance of following substances can be excluded, except negligible amounts on the level of natural / technical impurities.

Substance	CAS-No.
Asbestos	
Bromoethane	
Ammonium Nitrate	6484-52-2
4,4'-isopropylidenediphenol	80-05-7
Lithium Hydroxide	1310-65-2
Dimethylfumarate (DMF)	624-49-7
1,3,5-triazine-2,4,6-triamine	108-78-1

Table 3: Additional substances

19. Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) on 20 January 2009, Table 3.2 in Annex VI to CLP

This is to confirm that PA 2200 doesn't contain substances that are addressed in the Regulation 1272/2008 and listed in table 3.2 of Annex VI.

Date: August 19, 2014

Peter Keller
Manager Material and
Process Development

Thomas Tayarani
Regulatory Affairs Expert

Revision History

Version	Date	Author	Change Description
1.0	14-11-2012	T. Tayarani	Initial creation
2.0	08-07-2013	T. Tayarani	Document title changed to "Regulatory Information"; Global Automotive Declarable Substance List supplemented by Edition 2013 (GADSL), revised March 01, 2013
3.0	19-08-2014	T. Tayarani	Cross-checking data with SVHC candidate list dated 16-06-2014. None of the 155 listed substances are used within PA 2200.