Contents:

Material data sheet

PA 2200

1 General

Typical applications of the material are fully functional parts with high end finish right from the process, which easily withstand high mechanical and thermal load.

PA 2200 is suitable for processing on the following systems:

- EOSINT P 730, P 700
- EOSINT P 390, P 385, P 380i, P 380, with or without powder conveying system
  EOSINT P 360 with upgrade S&P, P 350/2 with upgrade 99 and upgrade S&P
- FORMIGA P 100

2 Technical data

General material properties

Average grain size	ISO 13320-11	56	µm
	Laser diffraction	2.20	mil
Bulk density	EN ISO 60	0.45	g/cm³
Density of laser-sintered part	EOS method	0.93	g/cm³
		58	lb/ft³

Mechanical properties

Tensile modulus	EN ISO 527	1700	MPa
	ASTM D638	247	ksi
Tensile strength	EN ISO 527	48	MPa
	ASTM D638	6962	psi

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Elongation at break	EN ISO 527	24	%
Elongation at break	ASTM D638	24	%
Flexural modulus	EN ISO 178	1500	MPa
	ASTM D790	217	ksi
Flexural strength	EN ISO 178	58	MPa
	ASTM D790	8412	psi
Charpy - Impact strength	EN ISO 179	53	kJ/m²
Charpy - Notched impact strength	EN ISO 179	4.8	kJ/m²
Izod – Impact strength	EN ISO 180	32.8	kJ/m²
Izod – Notched impact strength	EN ISO 180	4.4	kJ/m²
Ball indentation hardness	EN ISO 2039	78	N/mm²
Shore D - hardness	ISO 868	75	-
	ASTM D2240	75	-

The mechanical properties depend on the x-, y-, z-position and on the exposure parameters used.

Thermal properties

Melting point	EN ISO 11357-1	172 - 180	°C
Vicat softening temperature B/50	EN ISO 306	163	°C
	ASTM D1525	325	°F
Vicat softening temperature A/50	EN ISO 306	181	°C
	ASTM D1525	358	°F

The data are based on our latest knowledge and are subject to changes without notice. They do not guarantee properties for a particular part and in a particular application.

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PA 2200

PA 2200 is a non-filled powder on basis of PA 12.

General Properties

Property	Measurement Method DIN/ISO	Units	Value
Water absorption	ISO 62 / DIN 53495		
100°C, saturation in water		%	1.93
23°C, 96% RF		%	1.33
23°C, 50% RF		%	0.52

Property	Measurement Method DIN/ISO	Unit	Value
Coefficient of linear thermal expansion	ISO 11359 / DIN 53752-A	$x10^{-4}/K$	1.09
Specific heat	DIN 51005	J/gK	2.35

Thermal properties of sintered parts

Property	Measurement Method DIN/ISO	Unit	Value
Thermal conductivity	DIN 52616		
vertical to sintered layers		W/mK	0.144
parallel to sintered layers		W/mK	0.127

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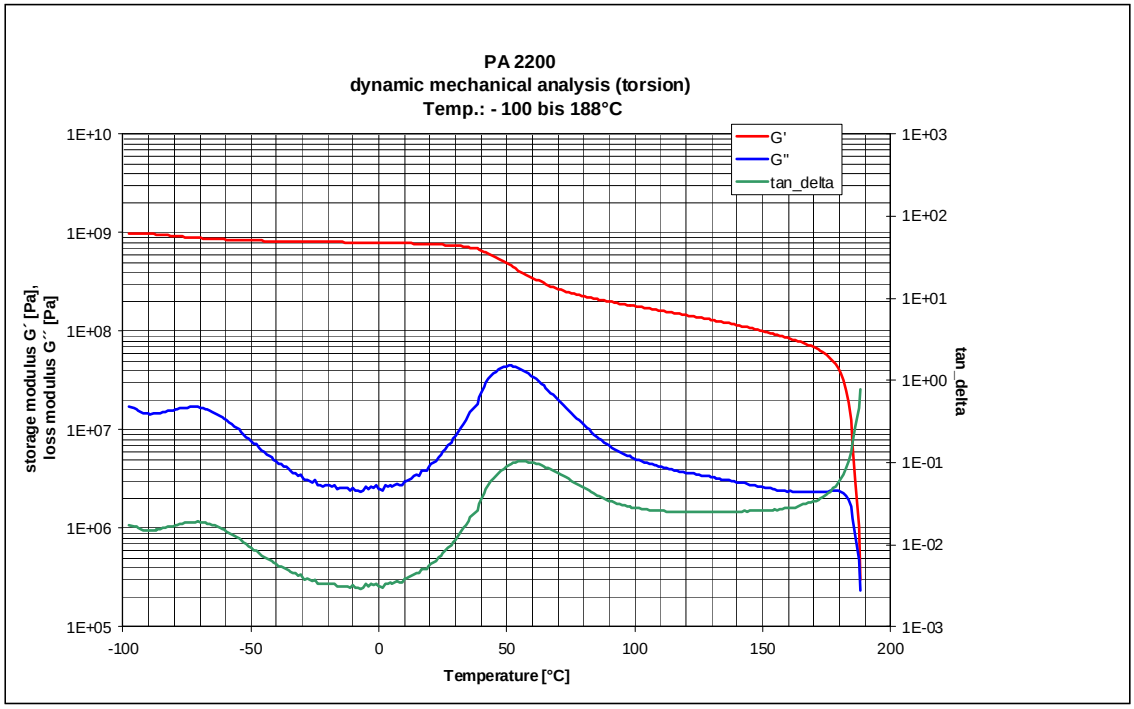
Short term influence of temperature on mechanical properties

An overview about the temperature dependence of mechanical properties of PA 12 can be retrieved from the curves for dynamic shear modulus and loss factor as function of temperature according to ISO 537.



In general parts made of PA 12 show high mechanical strength and elasticity under steady stress in a temperature range from - 40°C till + 80°C. Short time loading of parts made of PA 12 without stress is possible up to 160°C.

Long term properties under mechanical load and temperature

In general thermoplastics have higher mechanical strength under short term load then under long term load (> 1000 h) as result of creep. This occurs mostly at higher temperatures and leads to a reduction of modulus (creep modulus). Usually the creep resistance (mechanical properties under continuous load) is determined with the uniaxial tensile creep test (DIN 53444) under different loads and temperatures.

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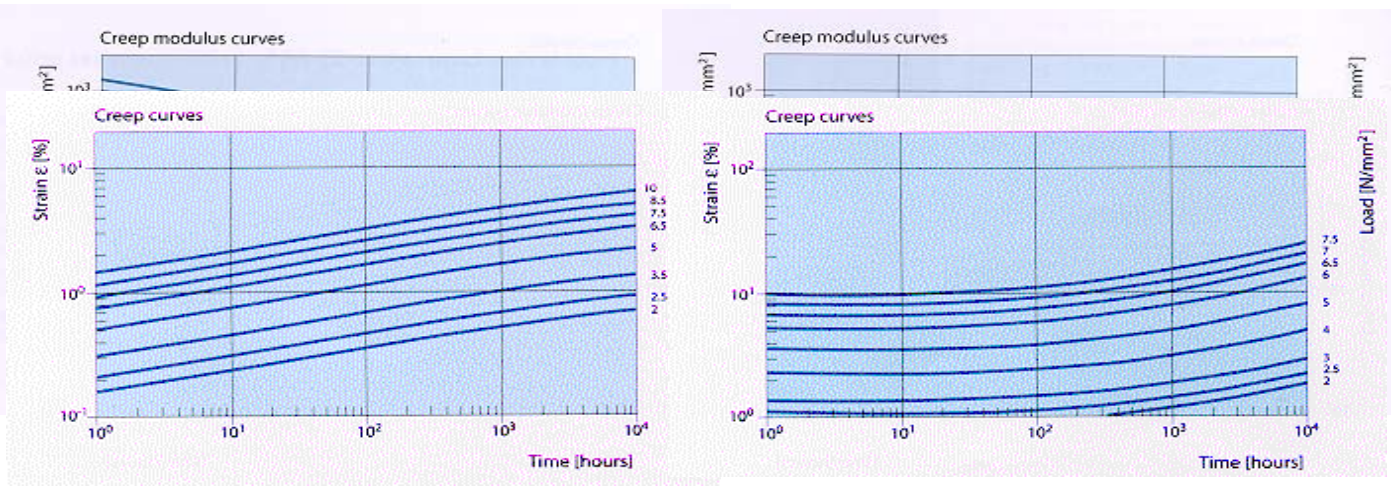
Creep modulus curces PA 12 at T = 23°/100°C



Creep elongation curves PA 12 at T = 23°C/100°C

Electrical Properties

Property	Measurement Method DIN/ISO	Unit	Value
Volume Resistance	DIN 53482 IEC-Publ. 93	Ω*cm	10^{13} –10^{15}
Surface Resistance	DIN 53482 IEC-Publ. 93	Ω	10^{13}
Relative Permittivity (1 kHz)	DIN53483 IEC-Publ. 250	10^{2} Hz	3,8
Dielectric strength	DIN 53481	KV/mm	92
Dielectric dissipation faktor (1 kHz)	DIN 53483 IEC-Publ. 250	-	0.05 – 0.09

The electrical properties depend on temperature and relative air humidity strongly. The above mentioned values charakterize polyamide 12 at following conditions: storage at 23°C, 50% air humidity up to saturation.

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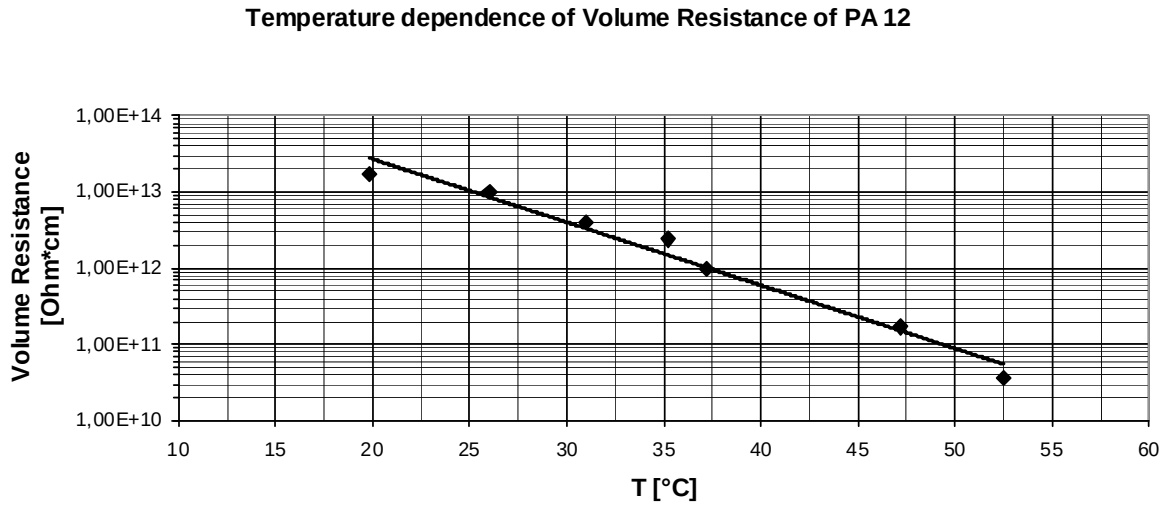
The details contained herein characterize the electrical behaviour of material and not of a specified building part. The details are based on our present state of knowledge and experience. We do, however, pass them without any warranty or property assurance.



Flammability / Burning Behaviour

The powder contains no flame retardants, parts made of PA 2200 can burn.

Property	Measurement Method DIN/ISO	Unit	Value
Flammability	IEC 60707 *		
	ISO 1210	Klasse (1,6 mm)	HB
	UL94*	Klasse (1,6 mm)	HB (horizontal burning)

*) flammability test as approval for electrical application

The details are based on our present state of knowledge and experience.
We do, however, pass them without any warranty or property assurance.

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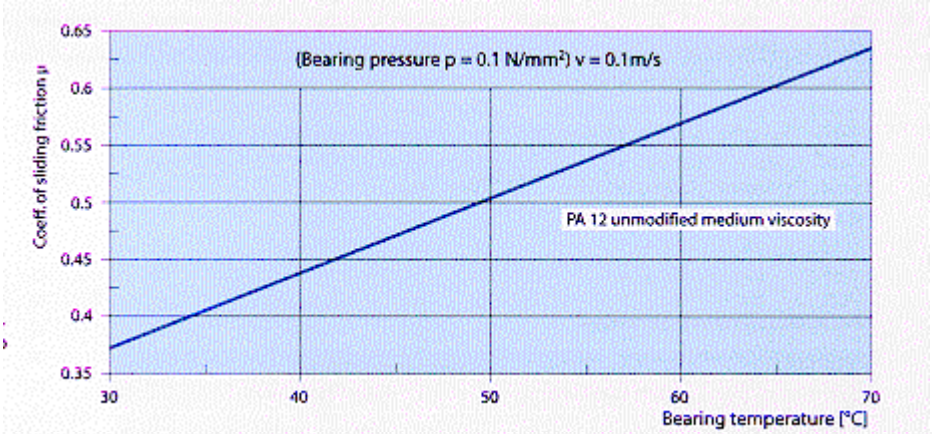
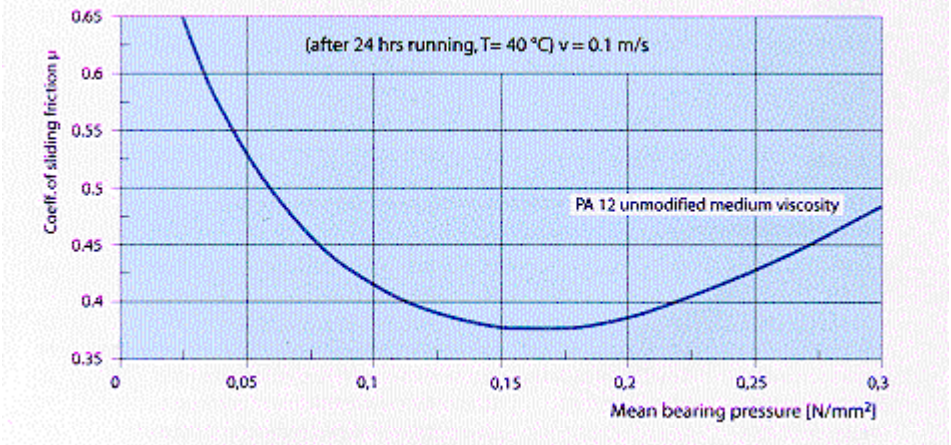
Frictional Properties, Abrasion and Wear

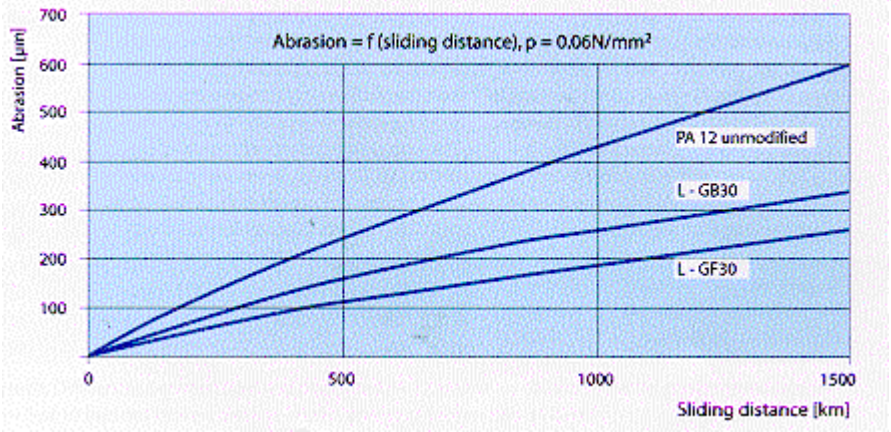
Polyamid 12 is characterized by a low coefficient of friction and by very good abrasion resistance.



Coefficient of sliding friction in dependence of bearing temperature (Lubrimeter test acc. A. Bartel)



Coefficient of sliding friction as function of pressure load (Lubrimeter test acc. A. Bartel))



Abrasion on bearing as function of the sliding distance and PA12-modification (L-GB30/glass spheres; L-GF30-glass fibres)

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Abrasion of sintered parts according to Taber-Test

Material	Measurement Method DIN/ISO	Unit	Value
PA 2200	DIN 53754	mg/2000 U	34
PA 3200 GF	DIN 53754	mg/2000 U	30

Chemical Resistance of PA 12

+ = resistant - = non-resistant ⊕ =practically resistant
O = conditional resistant ⊗ = litte resistant

Duration		6 Months	4 Weeks
Medium	**Concentration**	**20°C**	**60°C**
Aceton	100	+	+
Battery acid	10	⊗	-
Formic acid		+	O
Ammonia, aqueos solution	Conz.	+	+
Aniline	100	⊕	
Apple juice		+	+
Asphalt		+	+
Barium salts		+	+
Petrol		+	+
Benzene	100	+	O
Beer		+	
Break fluid		+	+
Butane Gas	100	+	+
Butane liquid	100	+	
Butter		+	

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Duration		6 Months	4 Weeks
Medium	**Concentration**	**20°C**	**60°C**
Chrome acid	10	-	-
Cyclohexanone	100	+	O
Dibutylphtalate (Vestinol®C)		+	+
Diethyl-Ether (Kp 35°C)	100	⊕	
Dioctylphtalate (Vestinol ®AH)		+	+
Dixan®Base	useable	+	+
Acetic acid	10	+	⊗
Ethyl-Acetate		+	⊕
Ethyl-Alkohol, denature	100	+	⊕
Fish		+	
Hydrofluoric acid	40	⊗	-
Anti freezer		+	+
Dishes cleaner		+	+
Glycerine	100	+	+
Glycol	100	+	+
Fuel Oil		+	+
coffee, drinkable		+	
Caustig	50	+	+
Potassium Chlorate aqueous solution	cold, saturated (7,3)	⊕	O
Potass. Permanganate aqueous solution	cold, saturated (6,4)	⊗	-
Linseed Oil		+	+

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Duration		6 Months	4 Weeks
Medium	**Concentration**	**20°C**	**60°C**
Methanol	100	+	⊕
Milk		+	+
Lactid Acid aqueous solution	10	⊕	O
Sodium-Chloride aqueous solution	cold saturated	+	+
Sodium-Hypochloride, aqueous solution	5	⊕	⊗
Sodium hydroxid	50	+	+
Ozone (0,5 ppm)		O	
Paraffin	100	+	+
Persil®Base	useable	+	+
Petroleum	100	+	+
Propane Gases	100	+	+
Pyridine	100	+	
Rum	40	+	+
Nitric Acid	10	-	-
Salt Acid	10	-	-
Soft Soap		+	+
Sulfur	100	+	+
Sulfur Acid	10	⊕	⊗
Sea Water		+	+
Silicon Oil		+	+
Edible Oil, animal + vegetable		+	+

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Prüfdauer		6 Monate	4 Wochen
Medium	**Konzentration**	**20°C**	**60°C**
Toluene	100	+	⊗
Tomato Juice		+	+
Trichlorethylene	100	O	⊗
Water	100	+	+
Hydrogen-Peroxide aqueous solution	30	+	
Whiskey	40	+	
Xylene	100	+	O
Citric acid aqueous solution	cold saturated	+	O
Lemon juice		+	+
Sugar solution	every	+	+

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Zertifikat , Biokompatibilität PA 2200

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

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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

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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.

EOS GmbH Electro Optical Systems · Robert-Stirling-Ring 1 · D-82152 Krailling

Declaration of Compliance

for materials made from plastic intended to come into contact with non-alcoholic foods based on FDA 21 CFR §175.300 (b)(3)xxxii (resinous and polymeric coatings) and FDA 21 CFR §177.1500 (a)(9) (nylon resins) with restriction as mentioned in §177.1500 (b)(9) and (b)

Manufacturer	EOS GmbH Electro Optical Systems Robert-Stirling-Ring 1 D-82152 Krailling/München
Date of issue	18 January 2019
Product Name	PA 2200 (product code: 9012-0014) and PA 2201 (product code: 9012-0019)
Compliance to regulations	Hereby we declare that the products PA 2200 and PA 2201 complies with its polymeric compositions with the following section of FDA 21 CFR §175.300 (b)(3)(xxxii)(resinous and polymeric coatings) and FDA 21 CFR §177.1500 (a)(9) (nylon resins) with restrictions as mentioned in §177.1500 (b)(9)(a) and (b).
Restrictions	There are restrictions in each of the regulations that must be taken into account by using PA 2200 and PA 2201. Users must review all applicable regulations and restrictions to assure compliance.

Dr. Hannes Gosther
Director Research and Development

Thomas Tayarani
Regulatory Affairs Specialist

Product Information EOSINT P/ PA2200-Pulver

PA2200 is a fine-powder on the basis of polyamide 12. In comparison to standard polyamide 12 PA2200 is characterized by higher cristallinity and higher melting point as result of specific production process. PA2200 contains stabilizers against oxidation.

Powder Properties

Property	Measurement Method DIN/ISO	Unit	Value
Bulk density	DIN 53466	g/cm3	> 0,430
Mean grain size d50 grain size d10 grain size d90	Laser diffraction (Malvern Mastersizer)	µm	58 40 90

General Properties

Property	Measurement Method DIN/ISO	Units	Value
Melting temperature Melting emthalpy Crystallization temperature	DSC	°C J/g °C	184 ca. 115 138
Water absorption 100°C, saturation in water 23°C, 96% RF 23°C, 50% RF	DIN 53495	 % 	 1,93 1,33 0,52
Coefficient of linear thermal expansion Specific heat	DIN 53752-A DIN 51005	x10^{-4}/K J/gK	1,09 2,35
Solution viscosity Molecular weight Mol mean M_n Weight mean M_w	EN ISO 307	Eta rel g/mol 	1,6 3000 9600

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*Density and Mechanical Properties of sintered parts**

Property	Measurement Method DIN/ISO	Unit	Value
Density	EOS-Methode	g/cm³	0,90 – 0,95
Tensile modulus	DIN EN ISO 527	N/mm²	1700 ± 150
Tensile strength	DIN EN ISO 527	N/mm²	45 ± 3
Elongation at break	DIN EN ISO 527	%	20 ± 5
Flexural modulus	DIN EN ISO 178	N/mm²	1240 ± 130
Charpy-Impact strength	DIN EN ISO 179	kJ/m²	53 ± 3,8
Charpy-Notched impact strength	DIN EN ISO 179	kJ/m²	4,8 ± 0,3
Izod-Impact strength	DIN EN ISO 180	kJ/m²	32,8 ± 3,4
Izod-Notched impact strength	DIN EN ISO 180	KJ/m²	4,4 ± 0,4
Ball indentation hardness	DIN EN ISO 2039	N/mm²	77,6 ± 2
Shore-D-hardness	DIN 53505		75 ± 2

*Density and mechanical properties of sintered part depend on exposure parameters and on x,y,z-position in building room.

Thermal properties of sintered part

Property	Measurement Method DIN/ISO	Unit	Value
Vicat softening temperature B/50 A/50	DIN EN ISO 306	°C	 163 181
Thermal conductivity Vertical to sintered layers ..parallel to sintered layers	DIN 52616	W/mK	 0,144 0,127

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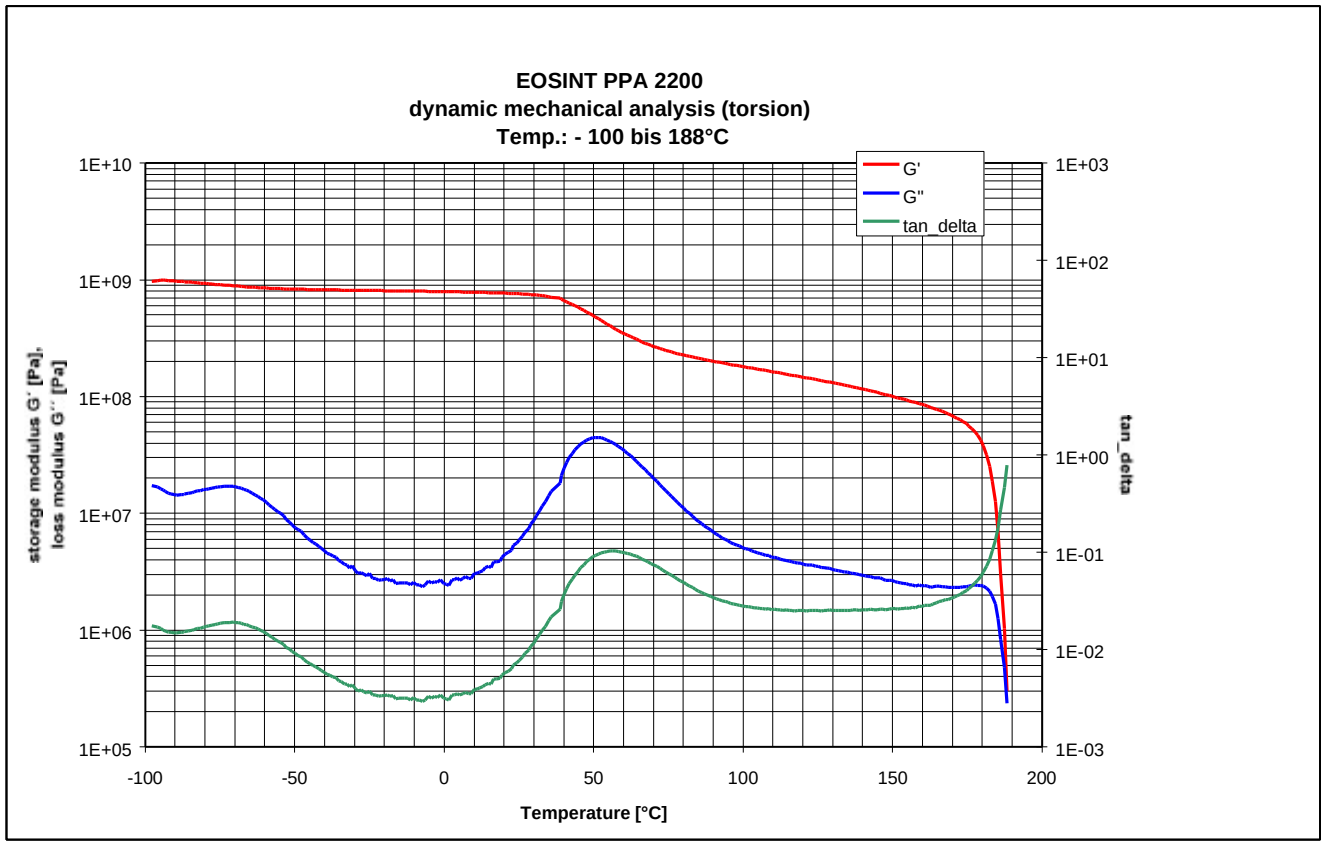
Short term influence of temperature on mechanical properties

A overview about the temperature dependence of mechanical properties of PA12 can be retrieved from the curves for dynamic shear modulus and loss factor as function of temperature according to ISO 537.



In general Polyamid12 – parts show high mechanical strength and elasticity under steady stress in a temperature range from - 40°C bis + 80°C. Short time loading of PA12-parts without stress is possible up to 160°C.

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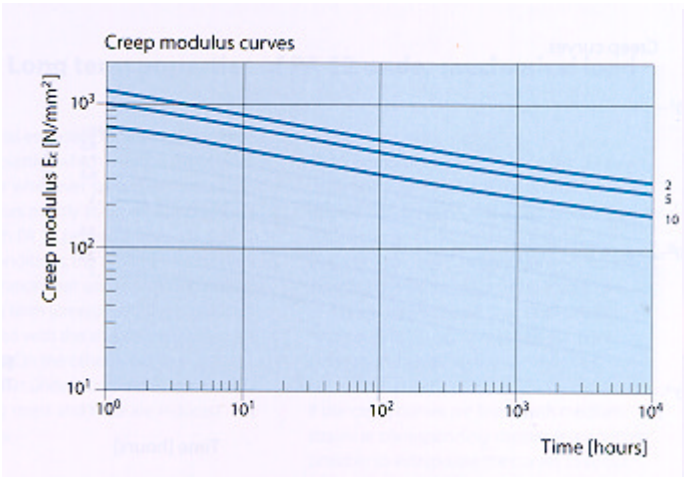
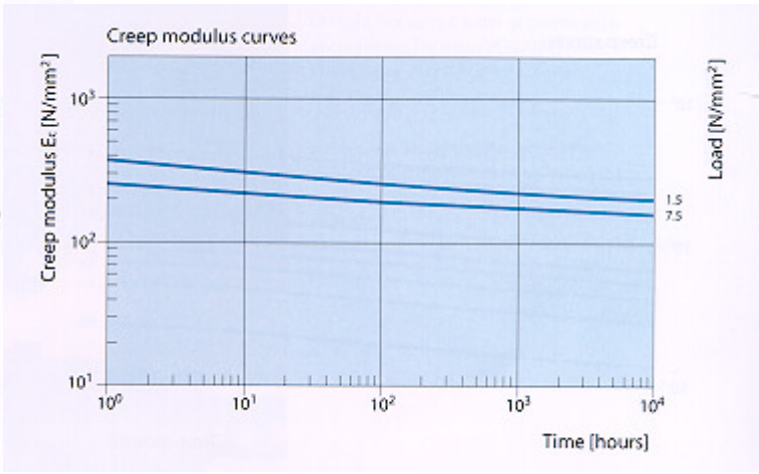
Long term properties under mechanical load and temperature

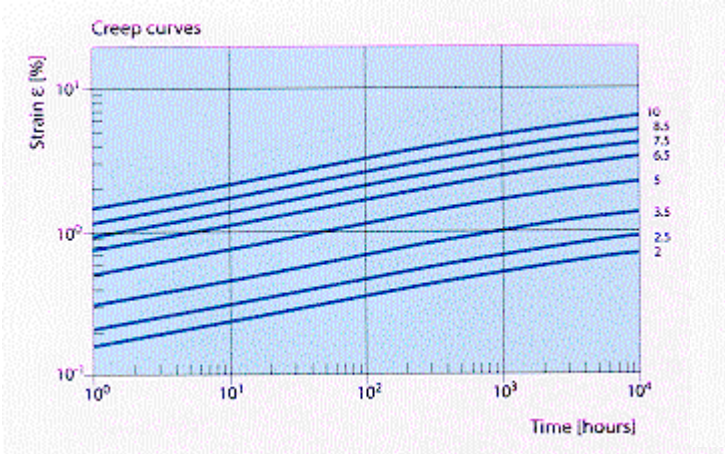
In general thermoplastics have higher mechanical strength under short term load then under long term load (> 1000 h) as result of creep. This occurs mostly at higher temperatures and leads to a reduction of modulus (creep modulus). Usually the creep resistance (mechanical properties under continous load) is determined with the uniaxial tensile creep test (DIN 53444) under different loads and temperatures.

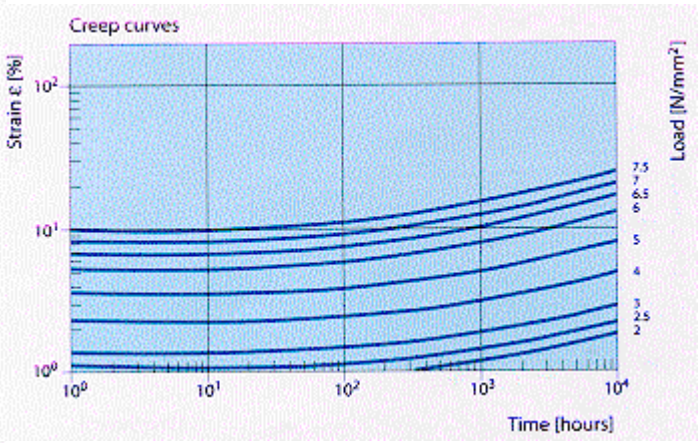
Creep modulus curves PA12 at T = 23°/100°C





Creep elongation curves PA12 at T = 23°C/100°C





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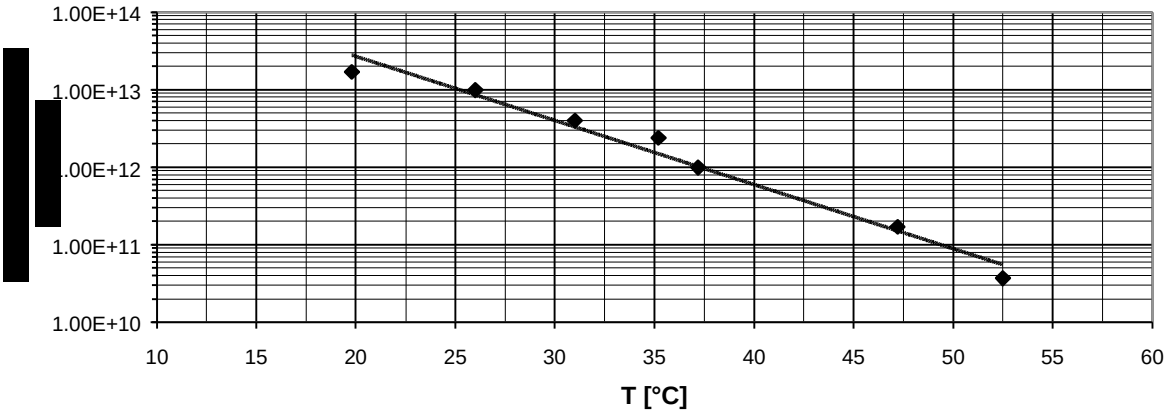
Electrical Properties

Property	Unit	Measurement Method DIN/ISO	Value
Volume Resistance	Ω*cm	DIN 53482 ICE-Publ. 93	10^{13} –10^{15}
Surface Resistance	Ω	DIN 53482 ICE-Publ. 93	10^{13}
Relative Permittivity(1 kHz)	10^{2} Hz	DIN53483 ICE-Publ. 250	3,8
Dielectric strength	KV/mm	DIN 53481	92
Dieelectric dissipation factor (1 kHz)	-	DIN 53483 ICE-Publ. 250	0,05 – 0,09

The electrical properties depend on temperature and relative air humidity strongly. The above mentioned values charakterize polyamide 12 at following conditions: storage at 23°C, 50% air humidity up to saturation.
The details contained herein characterize the electrical behaviour of material and not of a spezified building part. The details are based on our present state of konowledge and experience. We do, however, pass them without any warranty or property assurance.

Temperature dependence of Volume Resistance of PA12



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Flammability/ Burning Behaviour

The powder contains no flame retardants. So PA2200-parts can burn. Fillers like glass intensify flammability as result of wicking.
Flammable gases forms at temperature above 350°C. Combustion in excess air produces CO, CO_2, H_2O and nitrogen containing compounds as end products.

Property	Unit	Measurement Method DIN/ISO	Value
Ignition temperature	°C	DIN 51794	> 350°C
Flammability	class	IEC 60707* ISO 1210 (1,6 mm)	HB (horizontal burning)
Flammability	class	UL94* (3,2 mm)	HB (horizontal burning

* flammability test as approval for electrical application

The details contained herein characterize the burning behaviour of material and not of a spezified building part.
The details are based on our present state of konowledge and experience.We do, however, pass them without any warranty or property assurance.

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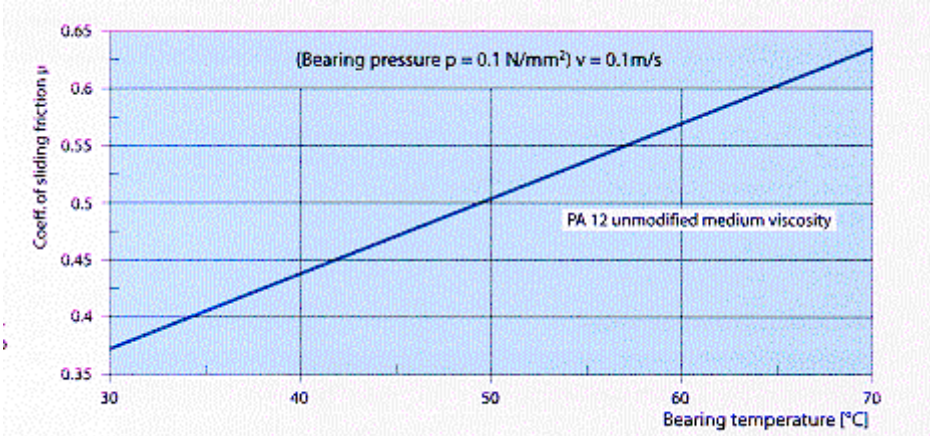
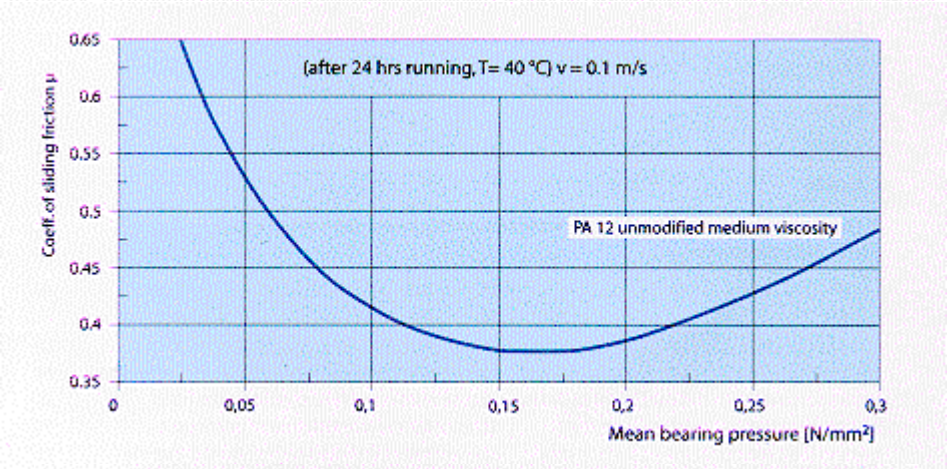
Frictional Properties, Abrasion and Wear

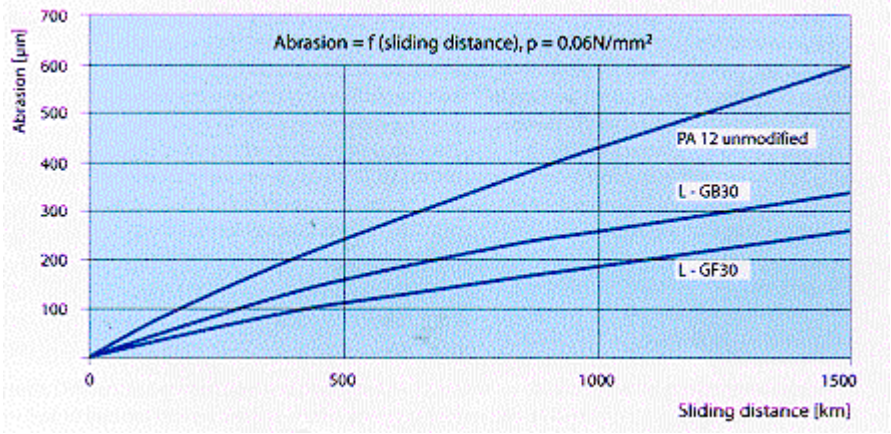
Polyamid 12 is characterized by a low coefficient of friction and by very good abrasion resistance.



Coeeficient of sliding friction in dependence of bearing temperature (Lubrimeter test acc. A. Bartel)



Coefficient of sliding friction as function of pressure load (Lubrimeter test acc. A. Bartel)



Abrasion on bearing as function of the sliding distance and PA12-modification (L-GB30/glass spheres; L-GF30-glass fibres)

Abrasion of sintered parts according to Taber-Test

Material	Unit	Method	Value
PA2200	mg	DIN 53754	34
PA3200GF			30

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Chemical Resistance of PA12

Duration		6 Month	4 Weeks
Medium	Concentration	20°C	60°C
Aceton	100	+	+
Battery acid	10	⊗	-
Formic acid		+	O
Ammonia, aqueous solution	Conz.	+	+
Aniline	100	⊕	
Apple juice		+	+
Asphalt		+	+
Barium salts		+	+
Petrol		+	+
Benzene	100	+	O
Beer		+	
Brake fluid		+	+
Butane Gas	100	+	+
Butane Liquid	100	+	
Butter		+	
Chlorine, liquid	100	-	-
Chrome bath, techn.		-	-
Chrome acid	10	-	-
Cyclohexanone	100	+	O
Dibutylphtalate(Vestinol®C)		+	+
Diethyl-Ether (Kp 35°C)	100	⊕	
Dioctylphtalate (Vestinol ®AH)		+	+
Dixan® Base	Useable	+	+
Acetic acid	10	+	⊗
Ethyl-Acetate		+	⊕
Ethyl-Alcohol, denature	100	+	⊕
Fish		+	
Anti freezer		+	+
Dishes cleaner		+	+
Glycerine	100	+	+
Glycol	100	+	+

+ = resistant - = non-resistant

⊕= practical resistant; O= conditional-resistant; ⊗= little resistant

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Chemical Resistance of PA12/ continued

Duration		6 Month	4 Weeks
Medium	Concentration	T = 20°C	T = 60°C
Fuel Oil		+	+
coffee, drinkable		+	
Caustig	50	+	+
Potassium Chlorate aqueous solution	cold saturated (7,3)	⊕	O
Potass. Permanganate aqueous solution	Cold saturated (6,4)	⊗	-
Linseed Oil		+	+
Magnesium Salts aqueous solution		+	+
Methylethyl-Ketone	100	+	O
Methanol	100	+	⊕
Milk		+	+
Lactid Acid aqueous solution	10	⊕	O
Sodium-Chloride aqueous solution	Cold saturated	+	+
Sodium-Hypochloride aqueous solution	5	⊕	⊗
Sodium hydroxid	50	+	+
Ozone (0,5 ppm)		O	
Paraffin	100	+	+
Persil® Base	useable	+	+
Petroleum	100	+	+
Propane Gases	100	+	+
Pyridine	100	+	
Rum	40	+	+
Nitric Acid	10	-	-
Salt Acid	10	-	-
Soft Soap		+	+
Sulphur	100	+	+
Sulphur Acid	10	⊕	⊗
Sea Water		+	+
Silicon Oil		+	+
Edible Oil, animal + vegetable		+	+

+ = resistant - = non-resistant

⊕= practical resistant; O= conditional resitant; ⊗= little resistant

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Chemical Resistance PA12/ continued

Duration		6 Month	4 Weeks
Medium	Concentration	20°C	60°C
Toluene	100	+	⊗
Tomato Juice		+	+
Trichlorethylene	100	O	⊗
Water	100	+	+
Hydrogen-Peroxide aqueous solution	30	+	
Whiskey	40	+	
Xylene	100	+	O
Citric acid aqueous solution	Cold saturated	+	O
Lemon juice		+	+
Sugar solution	every	+	+

+ = resistant - = non-resistant

⊕= practical resistant; O= conditional resistant; ⊗= little resistant

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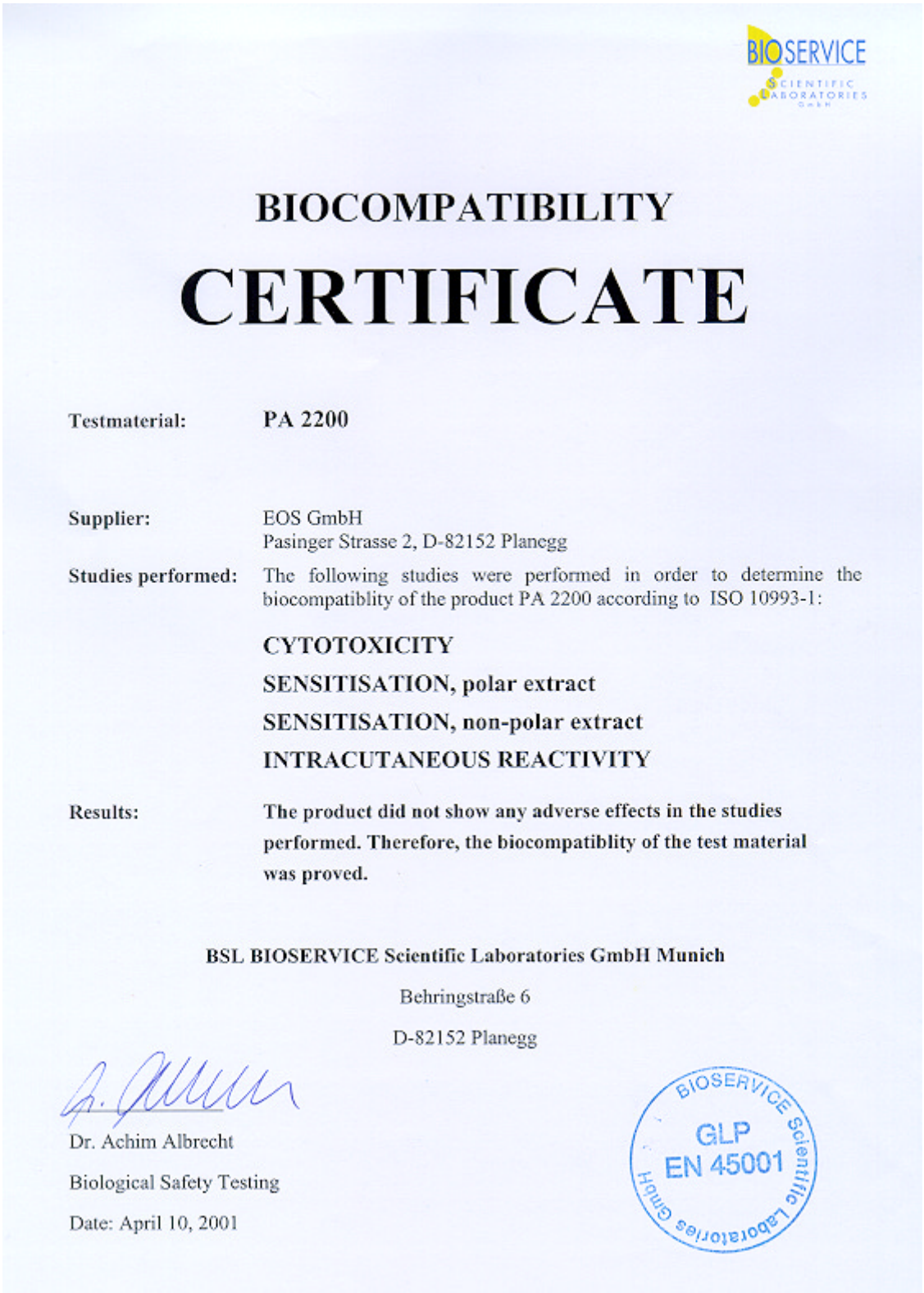
Approval Biocompatibility PA2200'



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

EOS GmbH Electro Optical Systems

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Telefax ++49 (0)89/856 85 -285
Internet: www.eos-gmbh.de

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

BIOCOMPATIBILITY

CERTIFICATE

Testmaterial: **Feinpolyamid PA 2200**
Chemical composition: Polylaurinlactam

Supplier: EOS GmbH; Electro Optical Systems
Robert-Stirling-Ring 1, 82152 Krailling; Germany

Studies performed: The following study was performed in order to determine the biocompatibility of the device.

USP BIOLOGICAL TESTS
(CLASSIFICATION VI/121 °C)

Results: **The test item did not show any effect in the performed study and meets all the criterias of the USP Biological Tests Classification VI.**

BSL BIOSERVICE Scientific Laboratories GmbH
Behringstraße 6
D-82152 Planegg

Dr. Ingrid Haist
Biological Safety Testing
Date: December 13, 2004

BSL BIOSERVICE Scientific Laboratories GmbH
GLP
ISO 17025

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

BSL BIOSERVICE Scientific Laboratories GmbH
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e-mail: info@bioservice.com · www.bioservice.com
Geschäftsführer: Dr. Wolfram Riedel
Amtsgericht München, HRB 109 770
Erfüllung und Gerichtsstand München
NORD/LB Norddeutsche Girozentrale, BLZ 250 500 00, Kto. 151 328 523, Swift-BIC: NOLADE2HXXX, IBAN: DE76 2505 0000 0151 3285 23
Deutsche Bank München, BLZ 700 700 24, Kto. 9 407 750, Swift-BIC: DEUTDEDBMUC, IBAN: DE52 7007 0024 0940 7750 00

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

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

BSL BIOSERVICE Scientific Laboratories GmbH
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e-mail: info@bioservice.com · www.bioservice.com
Geschäftsführer: Dr. Wolfram Riedel
Amtsgericht München, HRB 109 770
Erfüllung und Gerichtsstand München
NORD/LB Norddeutsche Girozentrale, BLZ 250 500 00, Kto. 151 328 523, Swift-BIC: NOLADE2HXXX, IBAN: DE76 2505 0000 0151 3285 23
Deutsche Bank München, BLZ 700 700 24, Kto. 9 407 750, Swift-BIC: DEUTDEDBMUC, IBAN: DE52 7007 0024 0940 7750 00

Sponsor

DyeMansion GmbH

Robert-Koch-Str. 1

82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH

Osteroda 38

04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04062

Mixed sample of:
DM Yellow R2, DM Red R3, DM Red R5, DM Red R6, DM Blue R4

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the mixed sample DM Yellow R2, DM Red R3, DM Red R5, DM Red R6, DM Blue R4 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04062.

Herzberg, 21-Nov-2018

Study Director

Dipl.-Biol. Anja Vaeth

Managing Director

Dr. Christiane Freytag

Sponsor

DyeMansion GmbH

Robert-Koch-Str. 1

82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH

Osteroda 38

04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04061

Mixed sample of:
DM Yellow N1, DM Blue N1, DM Blue N3, DM Blue N5, DM Blue N6

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the mixed sample DM Yellow N1, DM Blue N1, DM Blue N3, DM Blue N5, DM Blue N6 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04061.

Herzberg, 21-Nov-2018

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Test certificate

based on results of GLP study Lab. No. 04059

Mixed sample of:
DM Brown N1, DM Brown N2, DM Red N1, DM Red N2, DM Red N4

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the mixed sample DM Brown N1, DM Brown N2, DM Red N1, DM Red N2, DM Red N4 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04059.

Herzberg, 21-Nov-2018

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Test certificate

based on results of GLP study Lab. No. 04087

DM Blue N7
Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Blue N7 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04087.

Herzberg, 25-Jan-2019

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Test certificate

based on results of GLP study Lab. No. 04088

DM Yellow N3
Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Yellow N3 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04088.

Herzberg, 25-Jan-2019

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Test certificate

based on results of GLP study Lab. No. 04089

DM Red N7
Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Red N7 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04089.

Herzberg, 25-Jan-2019

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Test certificate

based on results of GLP study Lab. No. 04090

DM Grey N1
Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Grey N1 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04090.

Herzberg, 25-Jan-2019

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Test certificate

based on results of GLP study Lab. No. 04091

DM Black N1 EOS
Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Black N1 EOS is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04091.

Herzberg, 25-Jan-2019

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Test certificate

based on results of GLP study Lab. No. 04104

Mixed sample of the 5 test items: DM Yellow N3, DM Brown N2, DM Red N4, DM Blue N3, DM Black N1 EOS

***In vitro* skin irritation test on medical device extracts using reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 5 test items DM Yellow N3, DM Brown N2, DM Red N4, DM Blue N3 and DM Black N1 EOS each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04104.

Herzberg, 12-Apr-2019

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Test certificate

based on results of GLP study Lab. No. 04105

Mixed sample of the 4 test items: DM Yellow R2, DM Red R5, DM Red R6, DM Blue R4

***In vitro* skin irritation test on medical device extracts using reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 4 test items DM Yellow R2, DM Red R5, DM Red R6 and DM Blue R4 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04105.

Herzberg, 12-Apr-2019

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Test certificate

based on results of GLP study Lab. No. 04106

Mixed sample of the 4 test items: DM Red N2, DM Blue N1, DM Blue N5, DM Blue N6

***In vitro* skin irritation test on medical device extracts using reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 4 test items DM Red N2, DM Blue N1, DM Blue N5 und DM Blue N6 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04106.

Herzberg, 12-Apr-2019

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Test certificate

based on results of GLP study Lab. No. 04107

Mixed sample of the 4 test items: DM Red N1, DM Red N7, DM Blue N7, DM Grey N1

***In vitro* skin irritation test on medical device extracts using reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 4 test items DM Red N1, DM Red N7, DM Blue N7 and DM Grey N1 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04107.

Herzberg, 12-Apr-2019

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Test certificate

based on results of GLP study Lab. No. 04108

Mixed sample of the 3 test items: DM Yellow N1, DM Brown N1, DM Red R3

***In vitro* skin irritation test on medical device extracts using reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 3 test items DM Yellow N1, DM Brown N1 and DM Red R3 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04108.

Herzberg, 12-Apr-2019

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