

PA 2200
Product code: 9012-0014
Regulatory Information

Regulatory Information on PA 2200

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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 <https://eos.materialdatacenter.com/eo/standard/main/ds>.

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 10993-12: 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 10993-12: 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. Regulation (EU) No 10/2011 on Plastic Materials and Articles intended to come into Contact with Food

The laser sintered test specimen PA 2200 have been investigated regarding overall migration (OML) and specific migration according (SML) to requirements on plastic materials which are intended to come into contact with food of [Regulation \(EU\) No 10/2011](#) (lastly amended by [Regulation \(EU\) No 202/2014](#)) as well as in [Regulation \(EC\) No 1935/2004](#), as amended and in accordance with §§ 30, 31

of the German Food and Consumer Goods Act [LFGB](#). When used as specified, the overall migration as well as the specific migration does not exceed the legal limits.

The above mentioned samples are in compliance with the overall migration limit (OML) and specific migration limits (SML) of the used heat stabiliser and lauro lactam in contact with all kind of food (except alcoholic foods) at any long-term storage at room temperature and below including hot fill (e.g. 2 hours / 70°C or 15 min / 100°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 derivatives 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. (see <https://www.sec.gov/spotlight/dodd-frank/speccorpdisclosure.shtml>)

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. (see [US 21 CFR 801.437 \(b\)](#))

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
Hexabromobiphenyl	36355-01-8

Substance	CAS-No.
HCH, including lindane	608-73-1, 58-89-9

Table 1: Persistent Organic Pollutants (POPs)

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

This is to confirm that this product contains a chemical known to the State of California to cause cancer (see MSDS chapter 15). <https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations>

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).

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 occurrence of SVHC (Substances of Very High Concern) published in the "Candidate List" by ECHA under <https://echa.europa.eu/candidate-list-table> 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 2017 (GADSL), revised February 1, 2017

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 2017 can be downloaded from <http://www.gadsl.org/>.

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

Substance	CAS-No.
Amines (e.g. Diethanolamine) including tert. Amines	-
Ammonium Nitrate	6484-52-2
Asbestos	-
Bromoethane	-
1-Bromopropane	106-94-5
Complexing agent (e.g. EDTA, NTA, Citric acid)	-
Cyclic aliphatic bromide cluster (HBCD)	-
Dichloromethane	75-09-2
Dimethylfumarate (DMF)	624-49-7

Substance	CAS-No.
1,4-Dioxin	290-67-5
1,2,5,6,9,10-Hexabromocyclododecane	3194-55-6
n-Hexane	-
4,4'-isopropylidenediphenol	80-05-7
Lithium Hydroxide	1310-65-2
N-Methylpyrrolidone	872-50-4
Perylene-3,4,9,10-tetracarboxydiimide	81-33-4
Silicone compounds	-
Surfactants (Tensides)	-
Tetrachloroethylene	127-18-4
Tetrachloromethane	56-23-5
Toluene	-
1,3,5-triazine-2,4,6-triamine	108-78-1
Trichloroethylene	79-01-6

Table 2: Additional substances

19. Regulation (EC) No 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 \(EC\) No 1272/2008](#) and listed in table 3.2 of Annex VI.

20. End of Life Vehicles - Directive 2000/53/EC

The occurrence of the restricted substances by [Directive 2000/53/EC](#) can be excluded, except negligible amounts on the level of natural / technical impurities.

21. Polycyclic Aromatic Hydrocarbons (PAHs) - Directive 2005/69/EC, Polycyclic Aromatic Hydrocarbons - Regulation (EU) No 1272/2013 and Polycyclic Aromatic Hydrocarbons (PAHs) - EPA PAH 16

The occurrence of the below listed substances restricted by [Directive 2005/69/EC](#) - Polycyclic Aromatic Hydrocarbons, Polycyclic Aromatic Hydrocarbons - [Regulation \(EU\) No 1272/2013](#) and Polycyclic Aromatic Hydrocarbons - EPA PAH 16 can be excluded, except negligible amounts on the level of natural / technical impurities.

Substance	CAS-No.
Benzo(a)pyrene (BaP)	50-32-8
Benzo(e)pyren (BeP)	192-97-2
Benzo(a)anthracene (BaA)	56-55-3
Chrysene (CHR)	218-01-9
Benzo(b)fluoranthene (BbFA)	205-99-2
Benzo(j)fluoranthene (BjFA)	205-82-3
Benzo(k)fluoranthene (BkFA)	207-08-9
Dibenzo(a, h)anthracene (DBaHA)	53-70-3

Table 3: Substances regarding Directive 2005/69/EC and Regulation (EU) No 1272/2013

Substance	CAS-No.
Acenaphthene	83-32-9
Acenaphthylene	208-96-8
Anthracene	120-12-7
Benz[<i>a</i>]anthracene	56-55-3
Benzo[<i>b</i>]fluoranthene	205-99-2
Benzo[<i>k</i>]fluoranthene	207-08-9
Benzo[<i>ghi</i>]perylene	191-24-2
Benzo[<i>a</i>]pyrene	50-32-8
Chrysene	218-01-9
Dibenz[<i>a,h</i>]anthracene	53-70-3
Fluoranthene	206-44-0
Fluorene	86-73-7
Indeno[1,2,3- <i>cd</i>]pyrene	193-39-5
Naphthalene	91-20-3
Phenanthrene	85-01-8
Pyrene	129-00-0

Table 4: Substances regarding EPA PAH 16

22. Restriction on marketing and use of pentabromodiphenyl ether, octabromodiphenyl ether - Directive 2003/11/EC

The occurrence of pentabromodiphenyl ether and octabromodiphenyl ether restricted by [Directive 2003/11/EC](#) can be excluded, except negligible amounts on the level of natural / technical impurities.

23. Restriction on marketing and use of perfluorooctane sulfonates (PFOS) - Directive 2006/122/EC

The occurrence of perfluorooctane sulfonates (PFOS) mentioned in the [Directive 2006/122/EC](#) can be excluded, except negligible amounts on the level of natural / technical impurities.

24. Regulation (EU) No 517/2014 on fluorinated greenhouse gases

Ozone depleting substances listed as Class I and Class II substances in section 602 of the Clean Air Act (adoption of "The Montreal Protocol on Substances that Deplete the Ozone Layer") are not used in our recipe to produce PA 2200.

PA 2200 is made of raw materials of technical purity. Based on this the occurrence of ozone depleting substances can be excluded, except negligible amounts on the level of natural / technical impurities.

Date: January 19, 2017

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.
4.0	06-07-2015	T. Tayarani	Cross-checking data with SVHC candidate list dated 15-06-2015. None of the 163 listed substances are used within PA 2200.
5.0	22-01-2016	T. Tayarani	Cross-checking data with SVHC candidate list dated 20-01-2016. None of the 168 listed substances are used within PA 2200.
6.0	13-09-2016	T. Tayarani	Cross-checking data with Global Automotive Declarable Substance List supplemented by Edition 2016 (GADSL), revised March 14, 2016, Version 1.1; additional cross-checking data with SVHC candidate list dated 20-06-2016. None of the 169 listed substances are used within PA 2200.
7.0	16-02-2017	T. Tayarani	Chapter 14, cross-checking data with safe drinking water and toxic enforcement act of 1986, updated on January 27, 2017. Chapter 18, updated information on GADSL list V1.0 Edition 2017, additional substances added to table 2. Cross-checking data with SVHC candidate list dated 12-01-2017, none of the 173 listed substances are used within PA 2200. Added chapters 20, 21, 22 and 23.
8.0	01-08-2017	T. Tayarani	Updated chapter 4. Added chapter 24. Cross-checking data with SVHC candidate list dated 07-07-2017, none of the 174 listed substances are used within PA 2200.
9.0	19-01-2018	T. Tayarani	Cross-checking data with SVHC candidate list dated 15-01-2018, none of the 181 listed substances are used within PA 2200.