

According to Regulation (EC) 1907 / 2006

compiled: 17 April
2019

Version: 03 / 2019

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**Filaments based on PA 6.12
(Medex ®™ and Medex ®™ S
and Specialty Filaments derived
from them)**

Section 1: Identification of the substance / preparation and of the company

1.1 Product Identifier Filaments based on PA 6.12

1.2 Identified Use of the Substance or Preparation and advice against a specific use

Use: filament yarn
Identified Use: Dental and Personal Care Filaments

1.3 Data of the Supplier providing the Material Safety Data Sheet

Manufacturer/Supplier: Pedex GmbH
Hauptstraße Nord 67
69483 Wald-Michelbach / Germany
Tel.: +49 (0)6207 946-0
e-mail: holger.meid@perlon.com

1.4 Emergency Number: not applicable. This product is neither a hazardous substance nor a hazardous preparation. For information see section 1.3.

Section 2: Hazardous Identification

Physico-chemical Hazards: No particular hazards known.

Human Health Risks: Fibers processed at high speed may cause chafing or cuts. Protective measures are recommended.

At temperatures $\geq 150^{\circ}\text{C}$ the spin finish will degrade. Do not inhale vapours or smoke.

While cutting with hot knives toxic gases will be formed. Ventilation with fresh air is necessary. Do not inhale smoke or dust.

Other Hazards: none

Hazard Symbols: none

Section 3: Composition / Information on Ingredients

Range [%] Substance

> 96

Polymer mixture based on PA 6.12 Poly(hexamethylene-dodecanediamide); CAS: 26098-55-5 with functional additives and eventually with a colour agent

The fiber article may contain up to 0,1 weight percent of fiber preparation as a finish. This finish may generally be removed using an aqueous medium if necessary. The fibre article contains no residual solvent.

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Section 4: First Aid Measures

4.1 Description of First Aid Measures

General information:	not applicable
Inhalation:	Ensure supply of fresh air. In the event of symptoms apply for medical treatment.
Skin contact:	When in contact with the skin, clean with soap and water. In case of burning: After contact with molten product cool quickly with cool water or sterile salt solution and protect with gauze. Do not pull off solidified product from the skin forcibly. Apply for medical care.
Eye contact:	In case of contact with the eyes rinse thoroughly with plenty of water and apply for medical care. Show this Material Safety Data Sheet.
Ingestion:	No special measures necessary.

4.2 Important symptoms and effects, acute or delayed in time

After Inhalation of toxic fumes in the event of a smouldering fire: smoke intoxication. Seek medical advice immediately

4.3 Indication of medical emergency aid or special therapy

Symptomatic treatment

Section 5: Fire-fighting Measures

5.1 Suitable extinguishing media:

Water spray jet, foam, dry powder, carbon dioxide
Not suitable: full water jet

5.2 Special exposure hazards arising from the substance or preparation itself or combustion products

Unknown risk of formation of toxic pyrolysis products
Carbon Monoxide (CO), Carbon Dioxide (CO₂), Nitrogen Oxides, Hydrogen Cyanide, Soot

5.3 Special protective equipment for firefighters

Use self-contained breathing apparatus.
Do not inhale explosion and/or combustion gases.
Wear protective clothing and keep safety distance to avoid contact with the skin.
Avoid contamination of firefighting water into surface water, groundwater and soil.
Disposal of fire residues and contaminated firefighting water must be in accordance with the local regulations.

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Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation
Avoid formation of dust
Avoid inhalation of vapours, smoke and dust
Wear adequate protective clothing

6.2 Environmental protection

No special measures necessary.

6.3 Methods and material for retention and cleaning up

Collect scrap and depollute according to Section 13. Vacuum-clean any dust.

6.4 Reference to further Sections

Observe precautions of Sections 7 and 13.

7: Handling and Storage

7.1 Precautions for safe handling

Advice for safe handling: Avoid formation and deposition of dust.
Normal precautions for handling of molten, heated products must be observed.
Do not eat, drink and smoke in working areas.
Clean hands after contact with the product
Put away dirty working clothes and protective equipment before entering dining areas.

Advice on protection against fire and explosions: Dust can generate an explosive mixture with air.
Take precautions against static discharges.

7.2 Conditions for safe storage and clustering – Requirements to storage spaces and containers

No special measures
Ensure ventilation and unhindered access for firefighters.

Advices for clustering: none

Section 8: Exposure Controls / Personal Protection

8.1 Parameters to monitor

None
Critical values: Observe common airborne dust limit
Occupational exposure limits: dust - respirable fraction: Germany (TRGS 900) MAC: 3 mg/m3
- inhalable fraction: Germany (TRGS 900) WEL: 10 mg/m3

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8.2 Limits and Monitoring of Occupational Exposure / Personal Protective Equipment

Technical measures and implementation of adequate methods of operation have priority before using personal protective equipment.

Ensure adequate ventilation at workplaces.

Evaluations to judge safety precautions include technical and non technical methods of evaluation according to the general provisions of risk assessments.

Personal protective equipment	has to be selected for each specific workplace as a function of hazard
Respiratory protection:	Respiratory protection in the case of dust and/or thermal processing
Hand protection:	Gloves against cuts, chafing, heat-resistance according to risk assessment
Eye protection:	Safety glasses
Skin protection:	adequate working clothes
Limitation and monitoring of environmental exposure:	see Sections 6 and 7

Section 9: Physical and Chemical Properties**9.1 Data on basic physical and chemical properties****Appearance:**

Form:	filament
Aggregation state:	solid
Colour:	white or coloured
Odour:	odourless

Security relevant data

pH-value:	not applicable
Boiling point [°C]:	not applicable
Flash point [°C]:	not applicable
Inflammability [°C]:	not determined
Lower explosion limit:	not determined
Upper explosion limit:	not determined
Oxidising:	no
Vapour pressure [kPa]:	not applicable
Density [g/ml]:	1.02 – 1.10
Bulk density [kg/m³]:	not applicable
Solubility in water:	insoluble
Partition coefficient [n-octanol/water]:	not determined
Viscosity:	not applicable
Relative vapour density determined in air:	not applicable
Evaporation speed:	not applicable
Melting range [°C]:	210 - 220
Decomposition temperature [°C]:	≥ 300

9.2 Other information

none

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Section 10: Stability and Reactivity

10.1 Reactivity

Hazardous reactions: No hazardous reactions known

10.2 Chemical stability

At normal conditions the product is chemically stable up to the melting temperature

10.3 Potential of hazardous reactions

In intended use no hazardous reactions are expected

10.4 Conditions to prevent

Avoid temperatures > 300°C

10.5 Incompatible materials

Strong acids, strong bases and strong oxidants.

10.6 Dangerous decomposition products

Carbon Dioxide, Carbon Monoxide, Nitrogen Oxides, Hydrogen Cyanide, Soot

Section 11: Toxicological Information

11.1 Information on toxicological effects

At appropriate handling no negative effects are known after long-term experience

Practical experience:

No fibers with dimensions < 3 µm are contained in the product. The filaments are not respirable.
Fiber abrasion might cause skin irritation.

Section 12: Ecological Information

12.1 Toxicity

The product is not soluble in water. It is neither harmful for fish nor for bacteria.

12.2 Persistence and Biodegradability

The product is not biodegradable. Due to its low water-solubility it can be removed from water mechanically

12.3 Bioaccumulation Potential

The product does not accumulate biologically.
Keep the product away from animals to avoid it will be guzzled, filling their stomach.

12.4 Mobility in the Soil

The product remains in the soil until mechanical removal.

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12.5 Results of PBT-and vPvB-Assessment

According to the existing information the criteria for classification as PBT or vPvB are not fulfilled.

12.6 Other harmful Effects

No data available

Section 13: Disposal Considerations

13.1 Process of waste treatment

No dangerous waste according to Commission Decision 2000/532/EC including amendments. If recycling is not possible, the waste must be disposed of according to regulations of the local authorities.

Recommendation: Waste Classification according to 2000/532/EC should be agreed with the local disposal company.

Contaminated packaging: Films, broken spools with or without rest of monofilaments: 20 01 39 (plastics)
Cardboard boxes, cardboard packaging: 20 01 01 (Paper and Cardboard)

Cleaned packaging: Non contaminated and cleaned packaging can be recycled.
15 01 01: Paper and cardboard packaging
15 01 02: Plastic packaging

Section 14: Transport Information

14.1 UN-Number not applicable (no dangerous goods)

14.2 Correct UN Transport Information

ADR/RID no dangerous goods
IMDG-Code Not classified as „Dangerous Goods“
ICAO-TI / IATA-DGR Not classified as „Dangerous Goods“

14.3 Dangerous Materials Class

ADR / RID / IMDG-Code / ICAO-TI / IATA-GDR
Not applicable

14.4 Packaging Group Not applicable

14.5 Environmental Perils

Labelling of environmentally hazardous substances

ADR / RID / IMDG-Code: no
ICAO-IT / IATA-DGR: no

14.6 Precautionary Measures for user

See Sections 6 – 8

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Section 15: Regulatory Information

15.1. Prescriptions for Safety, Health and Environment / specific prescriptions for the product

EC Prescriptions

Regulation (EC) 1005 / 2009 (substances that deplete the ozone layer) – not applicable

Regulation (EC) 850 / 2004 (persistent organic pollutants) – not applicable

Regulation (EC) 689 / 2008 (export and import of dangerous chemicals) – not applicable

Regulation (EC) 648 / 2004 (detergents) – not applicable

Admission according Title VII of regulation (EC) 1907 / 2006: none

Restriction according Title VII of regulation (EC) 1907 / 2006: none

15.2 Product Safety Assessment

Not necessary, the product was not assessed

15.3 National Regulations

Water pollution class: not water pollutant (nwg)

Section 16: Other Information

Restrictions

This product is not appropriate for use in medical devices.

The information in this Material Safety Data Sheet represents the best available safe conditions to our knowledge at the date of its revision. The information intends to give evidence about storage, manufacturing, transport and disposal. The indications cannot be transferred to other products. If products of this MSDS will be mixed or processed together with other products, the indications cannot be transferred to the new manufactured material, except it is explicitly mentioned.

This chemical fibre is a product, not being subject to restrictions of the European Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Material Safety Data Sheets according to Article 31 or Chemical Safety Reports according to Article 14 of this Regulation are not needed. The Material Safety Data Sheet was compiled according to Annex II of this Regulation under the aspect of Responsible Care.