

Material Safety Data Sheet



Trade name: Polyamide 12 Mandibule Repositioning Device
Product no.: NOASTD/NOAPER
Current Version: 01 **Issued:** 16/03/2023 **Country:** Spain

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier**Trade name**

Polyamide 12

Substance name Polylaurolactam (polyamide 12) (CAS-No. 25038-74-8), modified, polymer

1.2 Relevant identified uses of the substance or mixture and uses advised against**Relevant identified uses of the substance or mixture**

Laser sintering

Uses advised against

No data available

1.3 Details of the supplier of the safety data sheet**Address**

OrthoApnea S.L.

Calle Flauta Magica, 22, 29006 Malaga, Spain

Phone: +34 951 20 43 34

Web: www.orthoapnea.com

Advice on Safety Data Sheetinternational@orthoapnea.com**Manufacturer****Address**

OrthoApnea S.L.

Calle Flauta Magica, 22, 29006 Malaga, Spain

Phone : +34 951 20 43 34

Web: www.orthoapnea.com

1.4 Emergency telephone

+34 951 20 43 34 (8 am – 8 pm Spain time)

SECTION 2: Hazards identification

2.1 Immediate hazards

No data available.

2.2 Potential Health Effects**Eye**

No hazard in normal industrial use.

Skin

No hazard in normal industrial use.

Inhalation

No hazard in normal industrial use.

Ingestion

No hazard in normal industrial use.

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SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical characterization

Substance name Polylauro lactam (polyamide 12) (CAS-No. 25038-74-8), modified, polymer

3.2 Mixtures

Not applicable. The product is not a mixture.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of persisting adverse effects, consult a physician. Change contaminated clothing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact

When in contact with the skin, clean with soap and water. After contact with molten product cool quickly with cold water. Do not pull solidified product from skin. Take for medical treatment.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Seek medical advice immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Foam; Carbon dioxide; Extinguishing powder; Water spray jet

Unsuitable extinguishing media

No data available.

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO₂); Carbon monoxide (CO); Nitrogen oxides (NO_x); Combustion products of this material have to be classed invariably as respiratory poison.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure - demand, MSHA/ NIOSH (approved or equivalent) and full protective gear.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid dust formation. Keep away sources of ignition.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

Take up mechanically. When picked up, treat material as prescribed under heading "Disposal considerations".

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

No special measures necessary if stored and handled as prescribed. Avoid the formation and deposition of dust. Provide good ventilation of working area (local exhaust ventilation if necessary).

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Provide eye wash fountain in work area. Do not inhale dust. Use barrier skin cream. Areas of the skin soiled with dust are to be cleaned with soap and water without delay, as the powder draws the natural moisture from the skin.

Advice on protection against fire and explosion

Dust can form an explosive mixture with air. Take precautionary measures against static charges. Keep away from sources of heat and ignition.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep containers dry, tightly closed, at temperatures between 41 and 95°F and relative air moisture of 20 – 70%.

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

None known

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limit values

No	Substance name	CAS no.	EC no.
1	DUST		
	List of approved workplace exposure limits (WELs) / EH40		
	Dust respirable		
	WEL long-term (8-hr TWA reference period)	4 mg/m ³	
	Comments	See Definition 44 "Dust"	

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List of approved workplace exposure limits (WELs) / EH40	
Dust inhalable	
WEL long-term (8-hr TWA reference period)	10 mg/m ³
Comments	See Definition 44 “Dust”

8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment

Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of dust formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified. Respirator with particulate filter (filter cat. P 3)

Eye / face protection

Safety glasses (EN 166)

Hand protection

Unless otherwise indicated in the chemical risk assessment, following recommendations are made: In case of intensive contact, wear protective gloves (EN 374). Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer’s instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves. In case of thermal processing, thermally insulating protective gloves are to be used.

Other

Wear fully closed, flame retardant clothing. Closed ESD safety footwear (ESD according to EN 61340-4-3 or equivalent).

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour
Powder
white

Odour
Odourless

Odour threshold
No data available

pH value
Not applicable

Boiling point / boiling range
Not applicable

Melting point / melting range	
Value	185 °C
Method	EN ISO 11357-1

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Melting point / melting range	
Value	> 300 °C

Flash point	
Not applicable	

Melting point / melting range	
Value	> 450 °C
Method	DIN 51794
Comments	Minimum ignition energy with inductance: 100–300 mJ

Auto-ignition temperature	
No data available	

Oxidising properties	
No data available	

Explosive properties	
No data available	

Flammability (solid, gas)	
No data available	

Lower flammability or explosive limits	
Value	30 g/m ³

Upper flammability or explosive limits	
No data available	

Vapour pressure	
Not applicable	

Vapour density	
No data available	

Evaporation rate	
No data available	

Relative density	
No data available	

Melting point / melting range	
Value	1.0 – 1.1 g/cm ³
Reference temperature	20 °C

Solubility in water	
Comments	insoluble

Solubility (ies)	
No data available	

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Partition coefficient: n-octanol/water
No data available

Viscosity
No data available

9.2 Other information

Other information
No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No data available.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

none, if handled according to order

10.6 Hazardous decomposition products

No hazardous decomposition products known

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity
No data available

Acute dermal toxicity
No data available

Acute inhalational toxicity
No data available

Skin corrosion/irritation
No data available

Serious eye damage/irritation
No data available

Respiratory or skin sensitisation
No data available

Germ cell mutagenicity
No data available

Reproduction toxicity
No data available

Carcinogenicity

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No data available

STOT-single exposure
No data available

STOT-repeated exposure
No data available

Aspiration hazard
No data available

Symptoms related to the physical, chemical and toxicological characteristics
Eye contact may cause mechanical irritation through dust particles.

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Inhalation of dusts may irritate the respiratory tract.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)	
Comments	No data available.

Toxicity to fish (chronic)
No data available

Toxicity to Daphnia (acute)	
Comments	No data available.

Toxicity to Daphnia (chronic)
No data available

Toxicity to algae (acute)	
Comments	No data available.

Toxicity to algae (chronic)
No data available

Bacteria toxicity
No data available

12.2 Persistence and degradability

Physico-chemical eliminability	
Comments	If used properly, this product does not cause problems, on the strength of previous experience.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

No data available.

12.7 Other information

Other information

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Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations

Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)

In accordance with the Reach regulation (EC) 1907/2006, the product does not contain any substances that are considered as subject to listing in annex XIV, inventory of substances requiring authorisation.

REACH candidate list of substances of very high concern (SVHC) for authorisation

In accordance with article 57 and article 59 of the Reach regulation (EC) 1907/2006, this substance is not considered as subject to listing in annex XIV, inventory of substances requiring authorisation ("Authorization list").

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

The substance is not subject to the provisions of annex XVII (restriction entries) of the Reach regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This substance is not subject to Part 1 or 2 of Annex I

15.2 Chemical safety assessment

No data available

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SECTION 16: Other information

Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case. EC

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

National Threshold Limit Values of the corresponding countries as amended in each case. Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Department issuing safety data sheet

OrthoApnea S.L.

Calle Flauta Magica, 22, 29006, Malaga, Spain.

Tel.: +34 951 20 43 34; e-mail: international@orthoapnea.com; web: www.orthoapnea.com

This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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