

PLGA filament filled with 10% hydroxyapatite

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 11/07/2024 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Name : PLGA filament filled with 10% hydroxyapatite
Product group : End product

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

Relevant identified uses

Use of the substance/mixture : 3D printing application

1.3. Details of the supplier of the safety data sheet

Lattice Medical
80, rue du Docteur Yersin
P.O. Box 59120
LOOS
FRANCE
T +33 6 73 59 08 71
contact@lattice-services.com

1.4. Emergency telephone number

Country/Area	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, the product does not present any particular risk, under normal conditions of use.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

To our knowledge, contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

To our knowledge, the mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Move the affected person away from the contaminated area and into the fresh air. If symptoms persist call a doctor.
First-aid measures after skin contact	: Wash with water and soap as a precaution. If case of redness or irritation, call a doctor.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult an eye specialist if necessary.
First-aid measures after ingestion	: Rinse mouth out with water. Do not give an unconscious person anything to drink. Do not induce vomiting. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : None known.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Carbon dioxide (CO₂). Water spray.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂).

5.3. Advice for firefighters

Firefighting instructions	: Cool down the containers exposed to heat with a water spray. Contain the extinguishing fluids by bunding.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate ventilation.

For non-emergency personnel

Emergency procedures : Evacuate the danger area. Do not touch or walk on the spilled product. Do not get in eyes, on skin, or on clothing. Eliminate every possible source of ignition.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Contain the spilled material by bunding. Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

For containment : Sweep or shovel spills into appropriate container for disposal.

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Methods for cleaning up : Wash non-recoverable remainder with large amounts of water.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For waste disposal after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Ensure that there is a suitable ventilation system. Avoid contact with skin, eyes and clothing. Keep away from ignition sources.
Hygiene measures : Do not drink, eat or smoke in the workplace. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep under inert gas. Protect from moisture. Keep away from ignition sources.
Incompatible materials : Water, humidity.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Eye and face protection

Eye protection:

Not required for normal conditions of use. If there is a risk of splashes : Safety glasses with side shields

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Not required for normal conditions of use. If there is a risk of splashes : Chemical resistant gloves (according to European standard NF EN 374 or equivalent)

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White.
Appearance	: filaments.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

To our knowledge, the product does not present any particular risk, under normal conditions of use.

10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Water, humidity.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)

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Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

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Persistence and degradability	No information available.

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose of in accordance with relevant local regulations.
Product/Packaging disposal recommendations	: Do not re-use empty containers.
Additional information	: The user's attention is drawn to the possible existence of specific european, national or local regulations regarding disposal.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

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ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

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Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service (division of the American Chemical Society)
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
ECHA	ECHA - European Chemicals Agency
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
vPvB	Very Persistent and Very Bioaccumulative

Data sources : ECHA - European Chemicals Agency. SDS of suppliers.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.