Polydioxanone PDO

Safety Data Sheet

compliant to Regulation (EC) No 1907/2006 (REACH) as amended by Regulation (EU) 2015/830 Date of issue: 06/07/2020 Version: 1.0

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

1.1. Product Identifier

Product form : Substance

Name : Polydioxanone - DIOXACTISSE 100

CAS N° : 31621-87-1 Synonyms : PDO

1.2. Identified relevant uses of the substance or mixture and use not recommended

1.2.1. Relevant identified uses

Use of substance/mixture: 3D printing application

1.2.2. Uses not recommended

This product cannot be implanted in humans.

1.3. Information about the provider of the safety data sheet

Lattice Medical
80, rue du Docteur Yersin
59120
LOOS - FRANCE
T +33 6 73 59 08 71

julien.payen@lattice-medical.com

1.4. Emergency call number

Country	Organization/Society	Address	Emergency number	Comment
France	ORFILA	http://www.centres- antipoison.net	+33 (0)8 00 59 59 59	

HEADING 2: Hazard Identification

2.1. Classification of the substance or mixture

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

Uncategorized

Adverse physicochemical effects on human health and the environment

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

2.2. Labelling elements

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

Labelling not applicable

2.3. Other hazards

Other hazards that do not result in classification: Dust can form an explosive mixture with air.

This substance/mixture does not fulfil the PBT criteria of reach regulation annex XIII

This substance/mixture does not meet the vPvB criteria of reach regulation annex XIII

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SECTION 3: Composition/Component Information

3.1. Substances

Name	Product Identifier	Classification according to Regulation (EC) No 1272/2008 [CLP]
Polydioxanone	(CAS No.) 31621-87-1	Uncategorized
3.2 Mixtures		

3.2 Mixtures

Not applicable

HEADING 4: First aid

4.1. Description of first aid

First aid after inhalation : Remove the subject from the contaminated area and bring him to the fresh air. If

symptoms persist, call a doctor.

First aid after skin contact : Wash immediately with soap and plenty of water while removing all contaminated

clothing and shoes. Seek immediate medical attention if symptoms appear.

First aid after eye contact : Rinse immediately and thoroughly with water, also under the eyelids, for at least 15

minutes. Seek immediate medical attention if symptoms appear.

First aid after ingestion : Rinse the mouth. Consult a doctor if symptoms appear.

4.2. Main symptoms and effects, acute and delayed

Symptoms/effects : None known

4.3. Indication of possible immediate medical care and special treatment required

Symptomatic treatment.

HEADING 5: Fire-fighting measures

5.1. Extinguishing means

Appropriate extinguishing means : Spray water, foam or carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products : By thermal decomposition (pyrolysis), releases: Carbon oxides (CO, CO2).

5.3. Advice to firefighters

Firefighting Instruction : Cool containers exposed to heat with sprayed water. Contain and contain extinguishing

fluids.

Fire protection : Do not intervene without appropriate protective equipment. Self-contained breathing

apparatus. Full protection of the body.

HEADING 6: Measures to be taken in the event of accidental dispersal

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure proper ventilation

6.1.1. For non-first aiders

Emergency procedures : Evacuate the danger zone. Do not touch or step on spilled product. Avoid contact with

eyes, skin or clothing. Prevent or limit the formation and dispersion of dust. Avoid any

possible source of ignition.

6.1.2. For first aiders

Emergency procedures : Do not intervene without appropriate protective equipment. For more information, see

section 8: "Control of exposure-personal protection".

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6.2. Precautions for environmental protection

Contain and contain land application. Do not discharge into sewers and rivers.

6.3. Containment and cleaning methods and equipment

For retention : Prevent or limit the formation and dispersion of dust. Sweep or shovel the spilled product

and put it in a suitable container for disposal.

Cleaning methods : Wash the non-recoverable remainder with plenty of water.

Other information : Dispose of solid materials or residues in a licensed centre

6.4. Reference to other headings

See section 13 for the disposal of waste resulting from clean-up.

HEADING 7: Handling and Storage

7.1. Precautions to be taken for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practices. Ensure proper

ventilation. Avoid dust formation. Avoid contact with skin, eyes or clothing. Do not breathe

in dust. Keep away from ignition sources.

: Do not drink, eat or smoke in the workplace. Wash hands after handling.

7.2. Conditions for safe storage, including possible incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep the container tightly closed.

Store under inert gas. Protect from moisture. Keep away from ignition sources.

Incompatible materials : Water, humidity Storage temperature : $-20 \,^{\circ}\text{C} \, / \, -4 \,^{\circ}\text{F}$

7.3. Specific end-use(s)

Hygiene measures

No additional information available.

HEADING 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available.

8.2. Exposure controls

Hand protection:

Not required under normal conditions of use. In case of risk of splashing: Gloves resistant to chemicals (according to the standard NF EN 374 or equivalent)

Eye protection:

Not required under normal conditions of use. In case of risk of splashing: Safety glasses with side protections

Protection of the skin and body:

Wear appropriate long-sleeved protective clothing.

Respiratory protection:

Adequate ventilation. In case of formation of vapours / dusts, use an approved respirator for dust protection

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HEADING 9: Physical and chemical properties

9.1. Information on essential physical and chemical properties

Physical state : Solid
Appearance : Filament

Colour : Variable. Transparent with golden reflections

Smell : Odorless.

Olfactory threshold : No data available : No data available ph Relative evaporation rate (butyl acetate=1) : No data available : ≈ 140 - 160 °C Melting point : No data available Freezing point Boiling point : No data available Flash point : Not applicable : No data available Auto-ignition temperature

Decomposition temperature : > 250 °C

Flammability (solid, gas) : No data available
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : No data available

Solubility : Insoluble

n-octanol/water partition coefficient (Log Pow) : No data available
Viscosity, kinematics : Not applicable
Viscosity, dynamic : Not applicable

Explosive properties : Dust can form an explosive mixture with air.

Oxidizing properties : Non-oxidizing according to EC criteria.

Explosive limits : No data available

9.2. Other information

Other properties : None

HEADING: Stability and responsiveness

10.1. Responsiveness

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

10.2. Chemical stability

Hydrolysis in water.

10.3. Possibility of dangerous reactions

Dust can form an explosive mixture with air.

10.4. Conditions to avoid

Avoid the formation of dust. The powdered material can form explosive dust-air mixtures.

10.5. Incompatible substances

Water, humidity (air)

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10.6. Hazardous decomposition products

No dangerous decomposition products are formed in the event of a fire: Carbon oxides.

HEADING 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral/dermal/inhalation)	: Unclassified (Based on available data, classification criteria are not met)
Skin corrosion/irritation	: Unclassified (Based on available data, classification criteria are not met)
Severe eye damage/eye irritation	: Unclassified (Based on available data, classification criteria are not met)
Respiratory or skin sensitization	: Unclassified (Based on available data, classification criteria are not met)
Germ cell mutagenicity	: Unclassified (Based on available data, classification criteria are not met)
Carcinogenicity	: Unclassified (Based on available data, classification criteria are not met)
Reproductive toxicity	: Unclassified (Based on available data, classification criteria are not met)
Specific target organ toxicity (single exhibition)	: Unclassified (Based on available data, classification criteria are not met)
Specific target organ toxicity	: Unclassified (Based on available data, classification criteria are not met)

Polydioxanone (31621-87-1)

Viscosity, kinematics Not applicable

HEADING 12: Ecological information

12.1. Toxicity

(repeated exposure)

Suction hazard

Hazards to the aquatic environment, short-term (acute) : Unclassified (Based on available data, classification criteria are not met)

Hazards to the aquatic environment, long-term (chronic): Unclassified (Based on available data, classification criteria are not met)

12.2. Persistence and degradability

Polydioxanone (31621-87-1)	
Persistence and degradability	Hydrolysis. Easily biodegradable.
10.0 01	

: Unclassified (Technical impossibility to obtain data)

12.3. Bioaccumulation potential

Polydioxanone (31621-87-1)	
Bioaccumulation potential	Non-bioaccumulative.

12.4. Mobility in soil

No additional information available

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12.5. Results of PBT and vPvB assessments

Polydioxanone (31621-87-1)

This substance/mixture does not fulfil the PBT criteria of reach regulation annex XIII

This substance/mixture does not meet the vPvB criteria of reach regulation annex XIII

12.6. Other adverse effects

No additional information available

HEADING 13: Disposal Considerations

13.1. Waste treatment methods

Waste treatment methods

: Dispose in accordance with applicable local requirements.

Recommendations for product/packaging processing

: Do not reuse empty containers.

Additional information

: The user's attention is drawn to the possible existence of specific laws, regulations and administrative provisions, Community, national or local, relating to disposal, concerning him.

European Waste Catalogue Code (EDC)

: 16 05 09 - discarded chemicals other than those specified in 16 05 06, 16 05 07 or 16 05 $^{\circ}$

HEADING 14: Transport information

In accordance with adr / RID / IMDG / IATA / AND requirements

ADR	IMDG	IATA	DNA	RID
14.1. UN number	14.1. UN number			
Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
14.2. UN proper shipping name				
Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
14.3. Transport hazard class(ies)				
Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
14.4. Packing group				
Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
14.5. Environmental hazards				
Unregulated	Unregulated	Unregulated	Unregulated	Unregulated

14.6. Special precautions to be taken by the user

Overland transport

Unregulated

Shipping

Unregulated

Air transport

Unregulated

Inland waterway transport

Unregulated

Rail transport

Unregulated

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14.7. Carriage in bulk in accordance with Annex II to the Marpol Convention and the IBC Code

Not applicable

HEADING 15: Regulatory Information

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

15.1.1. EU regulation

No restrictions according to Annex XVII of REACH

Polydioxanone is not on the REACH Candidate list

Polydioxanone is not listed in Annex XIV of REACH

Polydioxanone is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 on the export and import of dangerous chemicals

Polydioxanone is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National guidelines

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

HEADING 16: Other information

Abbreviations and acronyms:	
DNA	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CASE	Chemical Abstracts Service (division of the American Chemical Society)
CLP	Regulation on Classification, Labelling and Packaging; Regulation (EC) No 1272/2008
ECHA	ECHA - European Chemicals Agency
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods Code
РВТ	Persistent, bioaccumulative and toxic
REACH	Registration, evaluation, authorisation and restriction of chemical substances. REACH Regulation (EU) No 1907/2006
RID	International Regulations concerning the Carriage of Dangerous Goods by Rail
vPvB	Very persistent and very bioaccumulative

Data sources

: ECHA - European Chemicals Agency. Supplier SDS.

EU SDS (Annex II REACH)

This information is based on our current knowledge and describes the product for health, safety and environmental needs only. They should therefore not be interpreted as guaranteeing any specific property of the product.

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