

Revision date: 08/01/21 Version: 1 Language: en-GB Print Date: 08/01/21

SAFETY DATA SHEET

according to Regulation EC No.1907/2006 (REACH) and No.2015/830

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier.

Trade name : Neo TPU

Synonyms: Neo TPU reinforced by Nano-fiber, Filament 1.75mm/450gr; Neo TPU reinforced by Nano-

fiber, Pellets 650 gr; Neo TPU reinforced by Nano-fiber, Pellets 3 Kg; Neo TPU Nano-fiber

MasterBatch, Pellets 650 gr

Product Number : D2202; D2203; D2204; D2205

Brand : Medphen

Chemical Formula : Thermoplastic Polyurethane (O-(C6H4)-C(CH3)2-(C6H4)-CO

CAS Number : 75701-44-9

EC Number :

REACH No. : A registration number is not available for this substance as the substance or its uses are

exempted from registration, the annual tonnage does not require a registration or the

registration is envisaged for a later registration deadline.

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

Identified uses: Processing gears, housings, tubes and other uses in medical equipment.

Handles, overmolds, gaskets, rings and masks

Uses advised against :

1.3 Details of the supplier of the safety data sheet.

Company : MD Graphene SL

C/Dublín 19-III, 28232 Las Rozas, Madrid, España

Telephone : +34 910594185 E-mail address : reg@medphen.com

Web : https://www.medphen.com/

Additional information :

1.4 Emergency telephone number.

Emergency telephone number : Servicio de Información Toxicológica

+ 34 91 562 04 20

The information will be provided in Spanish (available 24h/365 days)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture.

Classification according to EC Regulation 1272/2008 (CLP Regulation):

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements.

Labelling according to EC Regulation 1272/2008 (CLP Regulation):

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Medphen - 42-D23-35 Page **1** of **9**

2.3 Other hazards.

Results of PBT and vPvB assessment:

No data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances.

Not aplicable.

3.2 Mixtures.

Substances presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008, for which Union workplace exposure limits have been assigned, classified as PBT/vPvB or included in the Candidate List.

This product contains no substances of very high concern in concentrations where an information obligation applies (REACH Regulation (EC) No. 1907/2006, Article 59).

Identifiers	Name	Chemical concentration	Classification	Specific concentration limits
-	-	-	-	-

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures.

General recommendations:

Do not ingest. If ingested, contact a poison control center immediately. Never give anything by mouth to an unconscious person. Consult a doctor.

In case of inhalation:

In case of inhalation of decomposition products, affected person should be moved into fresh air and kept still. In case of breathing difficulties administer oxygen. If breathing has stopped, give artificial respiration immediately. Seek medical attention.

In case of eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

In case of skin contact:

If irritation occurs, immediately wash with water and soap and rinse thoroughly. Do not remove product crusts which may have formed neither forcibly nor by applying any solvents to the skin involved. To obtain treatment for possible burns, and appropriate skin care, seek medical advice immediately.

If swallowed:

Rinse mouth for several minutes with water. Seek immediate medical advice.

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

May cause skin irritation or allergic reaction in some individuals

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

Treat symptomatically.

Medphen - 42-D42-36 Page **2** of **9**

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media.

Suitable extinguishing media:

CO2, extinguishing powder or water spray and dry chemical. Fight larger fires with water spray.

5.2 Special hazards arising from the substance or mixture.

In case of fire may be liberated: Carbon monoxide, carbon dioxide, small amounts of nitrogen oxides and traces of hydrogen cyanide.

5.3 Advice for firefighters.

Wear self-contained breathing apparatus for firefighting if necessary. Wear fully protective impervious suit.

5.4 Further information.

Do not allow water used to extinguish fire to enter drains, ground or waterways.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures.

Keep the molten mass away from the eyes and the skin. Avoid dust formation. Avoid breathing vapours, mist or gas. Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Provide adequate ventilation. Provide a conveniently located respiratory protective device. Keep unprotected persons away. Ensure adequate ventilation

6.2 Environmental precautions.

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

6.3 Methods and materials for containment and cleaning up.

Collect mechanically, use a suitable tight container

6.4 Reference to other sections.

For personal protection see section 8.

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling.

Provide appropriate exhaust ventilation at places where dust is formed. Provide good ventilation at the workplace.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities.

Store with desiccant in a cool, dry place. Store only in original container. Keep container tightly closed in a dry and well-ventilated place away from sources of ignition and oxidizers.

7.3 Specific end use(s).

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

Medphen - 42-D42-36 Page **3** of **9**

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters.

Components with workplace control parameters:

This product, as supplied, does not contain any hazardous materials with occupational exposure limits. No hazards are expected under normal use. The usual precautionary measures for handling chemicals should be followed. Keep away from

foodstuffs, beverages and feed.

Name	CAS number	Country	Control parameter (VLA, biological indicator, DNEL/DMEL, etc.)	Limit value
-	-	-	-	-

8.2 Exposure controls.

Specific considerations:

In case of melting: Provide for good ventilation or exhaust system or work with completely self-contained equipment.

Appropriate engineering controls:

If dust is generated during further processing provide exhaust ventilation.

General industrial hygiene practice.

Personal protective equipment:

Eye/face protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique to avoid skin contact with this product.

Chemically resistant gloves according to EN 374

In case of melting: Protective gloves against thermic risks according to EN 407.

Body Protection:

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. Wear suitable protective clothing. In case of dust formation: Overall

Respiratory protection:

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure:

No special environmental precautions required.

Medphen - 42-D42-36 Page **4** of **9**

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	:	Form: solid		
Color		Black		
Odour		No data available		
Odour Threshold		No data available		
pH	••	No data available		
Melting point/freezing point		No data available		
Initial boiling point and boiling range		No data available		
Flash point		No data available		
Evaporation rate		No data available		
Flammability (solid, gas)	:	No data available		
Upper/lower flammability or explosive limits	:	No data available		
Vapour pressure	••	No data available		
Vapour density	••	No data available		
Relative density	:	No data available		
Partition coefficient: n-octanol/water	:	No data available		
Auto-ignition temperature	:	No data available		
Decomposition temperature		>300°C		
Viscosity		No data available		
Explosive properties		No data available		
Oxidizing properties		No data available		
Nanoparticle size distribution		No data available		
Water solubility		No data available		
Redox potential		No data available		
Catalytic activity		No data available		
Zeta potential		No data available		
Aggregates and agglomerates stability		No data available		

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

9.2 Other safety information

Ignition temperature: >300°C

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

Exothermic reactions

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat /sun rays. Decomposition!

Avoid heat, sparks, flames and all other sources of ignition.

10.5 Incompatible materials

Strong oxidizing agents,

Medphen - 42-D42-36 Page **5** of **9**

10.6 Hazardous decomposition products

Thermal decomposition / conditions to be avoided:

Decomposition will not occur if used and stored according to specifications.

In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

To the best of our knowledge the acute and chronic toxicity of this substance is not fully known.

Skin corrosion/irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory or skin sensitization

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

IARC: Based on available data, the classification criteria are not met.

Reproductive toxicity

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

Aspiration hazard

No data available.

Additional Information

There are no known health risks.

The melted product can cause severe burns.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity.

No data available.

Medphen - 42-D42-36 Page **6** of **9**

12.2 Persistence and degradability

Product is not readily biodegradable.

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. PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects.

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods.

Product:

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging:

Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport following ADR / TPC regulations for road transport, RID for rail, IMDG for sea and ICAO / IATA for air transport.

14.1 UN Nuber.

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

Description:

ADR : Not dangerous goods IMDG : Not dangerous goods ICAO/IATA : Not dangerous goods

14.3 Transport hazard class(es).

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards.

ADR/RID: no IMDG: no IATA: no

Medphen - 42-D42-36 Page **7** of **9**

14.6 Special precautions for user.

No data available.

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

No data available.

SECTION 15: Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment.

For this product a chemical safety assessment was not carried out

Information about limitation of use:

For use only by technically qualified individuals.

SECTION 16: OTHER INFORMATION

Classification codes:

It is advisable to carry out basic training regarding occupational health and safety in order to handle the product correctly.

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.

OEL: Occupational Exposure Limit Value.

AS/NZS: Australian Standards/New Zealand Standards.

CAS: Chemical Abstracts Service. **CFR:** Code of Federal Regulations.

CLP: Classification, Labelling and Packaging.

DMEL: Derived minimal effect level. **DNEL:** Derived no-effect level **EC:** European Community **EN:** European Standard. **EU:** European Union

IATA: International Air Transport Association

IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IMDG Code: International Maritime Dangerous Goods Code

MARPOL: Pollution: The International Convention for the Prevention of Pollution from Ships

OSHA: Occupational Safety and Health Administration

PBT: Persistent, bioaccumulative and toxic **PNEC:** Predicted no-effect concentration

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals **RID:** Regulations Concerning the International Carriage of Dangerous Goods by Rail

TLV: Threshold Limit Value

vPvB: Very persistent and very bioaccumulative.

WEL: Workplace Exposure Limit

Further information:

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. The product should not be used for

Medphen - 42-D42-36 Page **8** of **9**

purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in current legislation.

Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, MD GRAPHENE SL expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN.

MD GRAPHENE SL has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by MD GRAPHENE SL for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, MD GRAPHENE SL strictly prohibits the use of any MD GRAPHENE SL products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. Besides, Medphen trademarks and the Medphen name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that

MD GRAPHENE SL allows, endorses or permits the use of MD GRAPHENE SL products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade MD GRAPHENE SL products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies). It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any post-market surveillance obligations. Any decision regarding the appropriateness of a particular MD GRAPHENE SL material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.

Medphen - 42-D42-36 Page **9** of **9**