	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 1 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

1- IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product

Commercial Name: DEFLEX PEEK

Product Description: Injectable PEEK For bridge framework, crowns and partial dentures

Manufacturer

Name: Nuxen S.R.L.
 Address: Sitio de Montevideo 2381, Lanús, Buenos Aires, Argentina
 Telephone: +54 11 4241 7762

Emergency Telephone Number

Nuxen S.R.L. Tel: +54 11 4241 7762 (M to F from 9 to 18)

2- HAZARDS IDENTIFICATION

Note: The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements


2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
 The substance is not classified, according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
 Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.

Hazard pictograms Void
 Signal word Void
 Hazard statements Void

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 2 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

2.3 Other hazards

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

3- COMPOSITION / INFORMATION ON INGREDIENTS

Pigmented PEEK (Polyether ether ketone)

4- FIRST AIDS

4.1 Description of first aid measures

General information:

Personal protection for the First Aider.

Take affected persons out of danger area and lay down.

Keep warm, position comfortably and cover well.

Do not leave affected persons unattended.

No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

After contact with the molten product, cool rapidly with cold water.

Do not pull solidified product off the skin.

Cover wound with a sterile dressing.

Call a doctor immediately.

After eye contact: Rinse opened eye for several minutes under running water.


After swallowing: If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 3 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

5- FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon monoxide (CO)

Under certain fire conditions, traces of other toxic gases cannot be excluded.

5.3 Advice for firefighters

Protective equipment: No special measures required.

6- ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Ensure adequate ventilation

Keep away from ignition sources.

6.2 Environmental precautions: Do not allow to penetrate the ground/soil.


6.3 Methods and material for containment and cleaning up: Pick up mechanically.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 4 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

7- HANDLING AND STORAGE

7.1 Precautions for safe handling

Store in cool, dry place in tightly closed receptacles.

Provide suction extractors if dust is formed.

No special measures required.

Information about fire - and explosion protection: Dust can combine with air to form an explosive mixture.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Store only in the original receptacle.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

7.3 Specific end use(s): No further relevant information available

8- EXPOSURE CONTROLS / PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace: Not required.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Do not eat, drink, smoke or sniff while working.

Use skin protection cream for skin protection.

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not necessary if room is well-ventilated.

Protection of hands: Heat protection gloves

Eye protection: Not required.

9- PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Granulate
Colour: Different according to colouring
Odour: Odourless
Odour threshold: Not determined.

pH-value: Not applicable.

Change in condition

Melting point/freezing point: 343 °C
Initial boiling point and boiling range: Undetermined

Flash point: Not applicable.

Flammability (solid, gas): Product is not flammable.

Ignition temperature: 575 °C

Decomposition temperature: Not determined.

Auto-ignition temperature: Not determined.

Explosive properties:
hazard. Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.
Upper: Not determined.

Vapour pressure: Not applicable.

Density at 20 °C: 1.3 g/cm³
Relative density at 20 °C: 1.3 - 1.5 g/cm³
Vapour density: Not applicable.
Evaporation rate: Not applicable.

Solubility in / Miscibility with water:

Insoluble.

Partition coefficient: n-octanol/water:

Not determined.

Viscosity:

Dynamic:

Not applicable.

Kinematic:

Not applicable.

Solvent content:

Organic solvents:

0.0 %

VOC (EC):

0,00 %

Solids content:

100.0 %

9.2 Other information: No further relevant information available.

10- STABILITY AND REACTIVITY

10.1 Reactivity: No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

Stable at environment temperature.

No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions: Reacts with strong acids and oxidising agents.


10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products:

Carbon monoxide and carbon dioxide

Poisonous gases/vapours

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 7 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

11- TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Primary irritant effect:

Skin corrosion/irritation No data available.

Serious eye damage/irritation No data available.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity Based on available data, the classification criteria are not met.

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

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

12- ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:


General notes: Generally not hazardous for water

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 8 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

13- DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation

Must be specially treated adhering to official regulations.

Smaller quantities can be disposed of with household waste.

Uncleaned packaging:

Recommendation:

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

14- TRANSPORT INFORMATION

14.1 UN-Number

ADR, ADN, IMDG, IATA

Void

14.2 UN proper shipping name

ADR

Void

ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class

Void

14.4 Packing group

ADR, IMDG, IATA

Void

14.5 Environmental hazards:

Marine pollutant:

No

14.6 Special precautions for user


Not applicable.

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

Not applicable.

UN "Model Regulation":

Void

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue Date: 29/10/2021 Page 9 of 9
	DEFLEX PEEK	IS PEEK Rev.: 01

15- REGULATORY INFORMATION

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

Labelling according to Regulation (EC) No 1272/2008	Void
Hazard pictograms	Void
Signal word	Void
Hazard statements	Void

Directive 2012/18/EU

Named dangerous substances - ANNEX I Substance is not listed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16- OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Issue Date: 29/10/2021

Issued by: Nuxen S.R.L.