	SAFETY INFORMATION <i>For Medical Devices</i>	Issue date: 29/10/2021 Pag. 1 de 5
	DEFLEX CLASSIC SR	IS CLASSIC Rev.: 02

1- IDENTIFICACION OF THE PRODUCT AND THE MANUFACTURER

Product

Commercial brand: DEFLEX CLASSIC SR

Product description: Polyamide for the manufacture of denture bases

Manufacturer

Name: Nuxen S.R.L.

Address: *Sitio de Montevideo 2381, Lanus Este, Buenos Aires, Argentina*

Phone: +54 11 4241 7762

Emergency information

Nuxen S.R.L. Tel: +54 11 4241 7762

Here goes the name of emergency control center of destination country(ies) and telephone number

2- IDENTIFICATION OF DANGERS

Health effects: in the form of granules, this material does not require special precautions beyond the implementation of GMP and industrial HSE

Flammability: Non flammable

Reactivity: Non reactive

3- COMPOSITION / INFORMATION ABOUT THE COMPONENTS

Formulation: Amorphous thermoplastic polyamide, incorporating calcinated metal inorganic pigments, antioxidants and mold release agents in a total percentage less than 0.7%



SAFETY INFORMATION
For Medical Devices

Issue date: 29/10/2021
Pag. 2 de 5

DEFLEX CLASSIC SR

IS CLASSIC
Rev.: 02

4- FIRST AIDS

Ingestion:	Get medical attention
Contact with skin:	Wash with soap and water
Contact with eyes:	Flush with water for at least 15 minutes. If necessary seek medical assistance
Inhalation:	Lead the person to fresh air. Supply oxygen if necessary. Depending on the severity seek medical assistance

Information for the intervenient practitioner

The molten polymer adheres to the bare skin. In case of occurrence, cool the affected area before removing the polymer adhered

5- FIREFIGHTING MEASURES

Flash point:	Non applicable
Self ignition temperature:	Non applicable
Flammability:	Grade HB according to IEC 60695-11-10

Firefighting procedure

Remove the source of heat or flame, use water fog, carbon dioxide, foam or dry chemical to extinguish the fire

Risks relating fire and explosion

Product NON explosive. It can burn reasonably quickly depending on external temperature and air supply.

Can release vapors of metal / oxide Carbon Monoxide (CO) / Hydrogen cyanide (HCN) during a fire



SAFETY INFORMATION
For Medical Devices

Issue date: 29/10/2021
Pag. 3 de 5

DEFLEX CLASSIC SR

IS CLASSIC
Rev.: 02

6- MEASURES IN CASE OF ACCIDENTAL RELEASE

Stop the spillage and collect in suitable container using traditional methods (broom and shovel). Contact local environmental authorities

7- HANDLING AND STORAGE

Store in a clean, well ventilated area, preferably at room temperature and away from foodstuffs

There are no products or materials incompatible with this product

Keep in its original packaging

8- EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye protection: The use of safety glasses is required

Skin protection: Required only for protection from abrasive effects. Wear gloves if necessary and wash hands after handling

Breathing protection: Required only when working near hot surfaces or cast, in order to avoid inhalation of vapors material. Avoid breathing dust

9- PHYSICAL AND CHEMICAL PROPERTIES

Boiling point:	Non applicable
Specific gravity:	1.00 g/cm ³
Melt point:	Non applicable
Glass transition temperature:	155 C
Vapor pressure:	Non applicable
Vapor density:	Non applicable
Solubility in water:	non soluble
Appearance / Odor:	Transparent or colored odorless pellets



SAFETY INFORMATION
For Medical Devices

Issue date: 29/10/2021
Pag. 4 de 5

DEFLEX CLASSIC SR

IS CLASSIC
Rev.: 02

10- STABILITY AND REACTIVITY

Stable under recommended storage and handling product.

It may be attacked by alkalis, acids and strong oxidizing agents.

11- TOXICOLOGICAL INFORMATION

LD 50 in Rats: Non applicable

TVL: Non applicable

12- ECOLOGICAL INFORMATION

The product usually does not present hazards to soil, air or water

13- INFORMATION REGARDING FINAL DISPOSAL


Follow local environmental regulations. Packaging contaminated with the product may not be reused for other purposes and should be eliminated

14- TRANSPORT INFORMATION

Product is not reached by any national or international regulation on the transport of dangerous substances. It has no specific recommendations on the UN list.

15- REGULATORY INFORMATION

This product is not subject to special provisions for the protection of persons or the environment at Community level

	SAFETY INFORMATION <i>For Medical Devices</i>	Issue date: 29/10/2021 Pag. 5 de 5
	DEFLEX CLASSIC SR	IS CLASSIC Rev.: 02

16- OTHER INFORMATION

The information contained in this document are based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements and should not be interpreted as a certificate of their specific properties.

Revision date: 29/10/2021

Prepared by: Nuxen S.R.L.