

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product name	REF
Tech2000 X-op	TECH510 / TECH110 / TECH210 / TECH310 / TECH410

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

Device for dental use, for professional use only (dentistry). Uses other than indicated are not recommended.

1.3. Details of the supplier of the safety data sheet**Medical device manufacturer:****Overfibers S.r.l.**

Via Malatesta, 7 40026 Imola (BO)

Phone +39 0542 52153 - FAX +39 0542 1900078

www.overfibers.com

Distributor:**Isasan S.r.l.**

Via Vincenzo Bellini, 17 22070 Rovello Porro (CO)

Phone +39 02 9675 4179

www.isasan.com/#

1.4. Emergency telephone number

Overfibers S.r.l. – Imola (BO) +39 0542 52153 (Business hours)

Poison Center Niguarda Ca' Granda – Milan +39 02 661 010 29

Poison Center Integrated Hospital - Verona 800 011858

Poison Center National Toxicological Information - Pavia 0382 24444

Poison Center Hospital Papa Giovanni XXIII - Bergamo 800 883300

Poison Center 'Careggi' Hospital Medical Toxicology Unit - Firenze 055 7947819


SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**




The product is classified as hazardous under the provisions of Regulation (EC) 1272/2008 (CLP) (as amended and adapted).

Classification	Hazard Statement
Acute toxicity – Category 4	H302 – Harmful if swallowed
Respiratory sensitisation – Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation – Category 1	H317 - May cause an allergic skin reaction
Skin irritation – Category 2	H315 - Causes skin irritation.
Serious eye damage – Category 1	H318 - Causes serious eye damage
Eye irritation – Category 2	H319 - Causes serious eye irritation
Specific target organ toxicity after single exposure – Category 3	H335 - May cause respiratory irritation
Chronic toxicity – Category 2	H411 - Toxic to aquatic life with long lasting effects

2.2 Label elements

The product is classified according to the CLP regulation.

GHS Pictograms:	Hazard Statement
	H302 - Harmful if swallowed
	H317 - May cause an allergic skin reaction
	H319 - Causes serious eye irritation
	H315 - Causes skin irritation.
	H335 - May cause respiratory irritation

	H318 - Causes serious eye damage
	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	H411 - Toxic to aquatic life with long lasting effects

Code	Precautionary Statements
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	If on skin: wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P305 + P351 + P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P301 + P310	If swallowed: immediately call a poison center or doctor/physician
P337 + P313	If eye irritation persists: Get medical advice/attention.
P332 + P313	If skin irritation occurs: Get medical advice/attention
P304 + P340	If inhaled: remove victim to fresh air and keep at rest in a position comfortable for breathing.
P273	Avoid release to the environment.
P501	Dispose of contents/container to in accordance with local/regional/national/international regulations in force at the time of disposal.

As mentioned in Title 1 - Article 1, point 5(d) of Regulation (EC) 1272/2008 (CLP/GHS): medical devices, as defined in Directive 93/42/EC intended for the end user and invasive or used in direct contact with the human body, are exempt from labelling.

2.3 Other hazards

According to the available data, the product does not contain any PBT (Persistent, Bioaccumulative and Toxic) or vPvB (Very Persistent and Very Bioaccumulative) substances.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Epoxy resin, catalysts, stabilisers, carbon fibres, glass powder, wax (anti-foaming) and fillers.

Other Components

No further information available.

SECTION 4: First aid measures

4.1 Description of first aid measures

General Information:

Avoid contact with the eyes.

In case of inhalation:

Carry the injured person to fresh air and keep him at rest in a position conducive to breathing.

In case of skin contact:

Wash thoroughly with soap and water.

In case of contact with the eyes:

Flush with running water for several minutes while holding the eyelids wide open. If pain persists: consult doctor.

In case of ingestion:

Contact a poison center or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Does not apply to this type of product.

5.2 Special hazards arising from the substance or mixture

No further information available.

5.3 Advice for firefighters

There are no special protective actions for firefighters.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

It does not apply to this type of product. These indications are valid for both workers and emergency workers.

6.2 Environmental precautions

Do not disperse in the environment.

6.3 Methods and material for containment and cleaning up

Does not apply to this type of product.

6.4 Reference to other sections

Personal precautions and protective equipment are detailed in Section 8.

Disposal conditions are detailed in section 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

No special precautions are necessary.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool place. Store inside its box or in another.

7.3 Specific end use(s)

None in particular.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

None in particular

8.2 Exposure controlsPersonal precautions:

Normal dental safety practices.

Protection devices:

Safety glasses for both dental staff and patients

Surgical gloves

Surgical mask.

Avoid breathing dust when cutting, wear a mask or cut using a liquid spray.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Proprietà	Valore
Physical state:	Solid
Colour:	Black
Odour:	Odourless
Odour threshold:	Not available
Melting point/freezing point:	Not available
Boiling point or initial boiling point and boiling range:	Not available
Flammability:	Not available
Lower and upper explosion limit:	Non-explosive product
Flash point:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
pH:	Not available
Kinematic viscosity	Not available
Solubility:	Insoluble in water
Partition coefficient n-octanol/water:	Not available
Vapour pressure:	Not available
Density and/or relative density:	Density: 1,6 g/cm ³
Relative vapour density:	Not available
Particle characteristics:	Not available

9.2 Other information

Information not available.

SECTION 10: Stability and reactivity**10.1 Reactivity**

Information not available.

10.2 Chemical stability

The product is stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Information not available.

10.4 Conditions to avoid

Information not available.

10.5 Incompatible materials

Information not available.

10.6 Hazardous decomposition products

Information not available.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

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

Skin corrosion/irritation: May cause skin irritation to those allergic to one of the components of the medical device.

Serious eye damage/irritation: Eye irritation may occur in case of unintentional contact.

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

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

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

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

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

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

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

11.2 Information on other hazards

The device does not consist of substances that have endocrine-disrupting properties.

SECTION 12: Ecological information

12.1 Toxicity

No further information available.

12.2 Persistence and degradability

No further information available.

12.3 Bioaccumulative potential

No further information available.

12.4 Mobility in soil

No further information available.

12.5 Results of PBT and vPvB assessment

According to the available data, the product does not contain any PBT (Persistent, Bioaccumulative and Toxic) or vPvB (Very Persistent and Very Bioaccumulative) substances.

12.6 Endocrine disrupting properties

The device does not consist of substances that have endocrine-disrupting properties.

12.7 Other adverse effects

No further information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

When disposing of this product, contact a company specialising in the disposal of medical and hospital waste. Observe all applicable European, federal, state and local environmental protection regulations when disposing of this product.

SECTION 14: Transport information

14.1 UN number or ID number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Class not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

No.

14.6 Special precautions for user

Not applicable.

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

This safety data sheet meets the requirements of Regulation (EC) No 1907/2006.

15.2 Chemical safety assessment

The commercial use of this material is regulated by the CE marking.

SECTION 16: Other information

The data are given to the best of our current knowledge. However, they do not represent any guarantee of the product characteristics and do not substantiate any contractual legal relationship.

Since the use of the product is not under our direct control, it is the user's responsibility to observe the applicable laws and regulations regarding hygiene and safety. We accept no liability for improper use.

16.1 Intended user

The device is only used by medical/dental and dental technicians. The use of the medical device must be carried out by medical/dental or dental technician personnel. The use of the medical device requires no special training as the procedure is part of the operator's cultural background.

Changes from previous revision

The entire safety data sheet has been updated according to current legislation.

Section 2 has been substantially updated.

This safety data sheet replaces Revision 00.