



According to Regulation (EC) No 1907/2006

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier	Zfx™ Polycarbonate splint
1.2. Relevant identified uses of the substance or mixture and uses advised against	<p>Use of the substance/mixture Zfx™ Polycarbonate splint are transparent dental milling blanks out of polycarbonate for the manufacture of splints, therapeutic splints, bite regulators and drilling templates for short-term application in the oral cavity up to 30 days.</p> <p>Uses advised against No information available.</p>
1.3. Details of the supplier of the safety data sheet	<p>Company name: Zfx GmbH Street: Kopernikusstr. 15 Place: D-85221 Dachau Telephone: 08131 - 332 440 Fax: 08131 - 332 44 10 e-mail: info@zfx-dental.com Contact person: Oliver Hill, Andreas Geier Internet: www.zfx-dental.com</p>
1.4. Emergency telephone number:	<p>+49 (0) 8131 - 332 440</p> <p>Further information No information available.</p>

2. Hazards identification

2.1. Classification of the substance or mixture	<p>Regulation (EC) No. 1272/2008 This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.</p>
2.2. Label elements	-
2.3. Other hazards	No information available.

3. Composition/information on ingredients

3.1. Substances	<p>Chemical characterization No information available.</p> <p>Further information No information available.</p>
------------------------	---

4075EN REV. 08/18 ©2018 Zfx GmbH & Zimmer Dental Inc. | Zimmer and the Zimmer logo are trademarks of Zimmer Inc. or its affiliates and Zfx and the Zfx logo are trademarks of Zfx GmbH, Germany. All other trademarks are the property of the respective owner.



4. First aid measures

4.1. Description of first aid measures	<p>After inhalation Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.</p> <p>After contact with skin After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.</p> <p>After contact with eyes Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.</p> <p>After ingestion IF SWALLOWED: Call a doctor if you feel unwell.</p>
4.2. Most important symptoms and effects, both acute and delayed	No information available.
4.3. Indication of any immediate medical attention and special treatment needed	No information available.

5. Firefighting measures

5.1. Extinguishing media	<p>Suitable extinguishing media Dry extinguishing powder. Carbon dioxide (CO₂). Alcohol resistant foam. Water spray jet</p> <p>Unsuitable extinguishing media High power water jet</p>
5.2. Special hazards arising from the substance or mixture	<p>In case of fire may be liberated: Carbon monoxide, Carbon dioxide, Nitrogen oxides (NO_x).</p> <p>Possible in traces: Hydrogen cyanide (hydrocyanic acid)</p> <p>Do not inhale explosion and combustion gases.</p>
5.3. Advice for firefighters	<p>Co-ordinate fire-fighting measures to the fire surroundings.</p> <p>In case of fire: Wear self-contained breathing apparatus.</p> <p>Additional information Do not allow run-off from fire-fighting to enter drains or water courses.</p>

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures	Use personal protection equipment.
6.2. Environmental precautions	Do not allow to enter into surface water or drains.
6.3. Methods and material for containment and cleaning up	Take up mechanically. Avoid dust formation. Collect in closed and suitable containers for disposal.
6.4. Reference to other sections	See protective measures under point 7 and 8. Disposal: see section 13



7. Handling and storage

<p>7.1. Precautions for safe handling</p>	<p>Advice on safe handling See section 8.</p> <p>Advice on protection against fire and explosion No special fire protection measures are necessary.</p> <p>Further information on handling Avoid dust formation. Protect from moisture. Provide adequate ventilation as well as local exhaustion at critical locations. To follow: Occupational exposure limit values</p>
<p>7.2. Conditions for safe storage, including any incompatibilities</p>	<p>Requirements for storage rooms and vessels Keep/Store only in original container.</p> <p>Advice on storage compatibility Keep the packing dry and well sealed to prevent contamination and absorption of humidity.</p> <p>Further information on storage conditions Keep away from: Frost, Heat Handle with care - avoid bumps, friction and impact.</p>
<p>7.3. Specific end use(s)</p>	<p>Zfx™ Polycarbonate splint are transparent dental milling blanks out of polycarbonate for the manufacture of splints, therapeutic splints, bite regulators and drilling templates for short-term application in the oral cavity up to 30 days.</p>

8. Exposure controls/personal protection

<p>8.1. Control parameters</p>	
<p>8.2. Exposure controls</p>	<p>Appropriate engineering controls Technical ventilation of workplace</p> <p>Protective and hygiene measures Work in well-ventilated zones or use proper respiratory protection. Only wear fitting, comfortable and clean protective clothing. Wash hands before breaks and after work. Separate storage of work clothes.</p> <p>Eye/face protection Suitable eye protection: Eye glasses with side protection goggles</p> <p>Hand protection Suitable gloves type: NBR (Nitrile rubber) DIN EN 374, Butyl caoutchouc (butyl rubber) DIN EN 374, PVC (Polyvinyl chloride) Thickness of the glove material: >0,5 mm Wear cotton undermitten if possible. Breakthrough times and swelling properties of the material must be taken into consideration.</p>



8.2. Exposure controls

Skin protection

Protective clothing.

Respiratory protection

Particle filter device (DIN EN 143)

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid
Colour:	transparent
Odour:	odourless
Test method	
pH-Value:	not determined
Changes in physical state	
Melting point:	not determined
Initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined
Flammability	
Solid:	>450 °C
Gas:	not applicable
Explosive properties	
No information available.	
Lower explosion limits:	not applicable
Upper explosion limits:	not applicable
Auto-ignition temperature	
Solid:	not determined
Gas:	not determined
Decomposition temperature:	not determined
Oxidizing properties	
Not oxidizing.	
Vapour pressure:	not determined
Density:	not determined
Bulk density:	600-700 kg/m ³
Water solubility:	insoluble
Solubility in other solvents	
No information available.	
Partition coefficient:	not applicable
Viscosity / dynamic:	not determined
Vapour density:	not determined
Evaporation rate:	not determined
9.2. Other information	No information available.

4075EN REV. 08/18 ©2018 Zfx GmbH & Zimmer Dental Inc. | Zimmer and the Zimmer logo are trademarks of Zimmer Inc. or its affiliates and Zfx and the Zfx logo are trademarks of Zfx GmbH, Germany. All other trademarks are the property of the respective owner.



10. Stability and reactivity

10.1. Reactivity	No information available.
10.2. Chemical stability	No information available.
10.3. Possibility of hazardous reactions	In case of fire may be liberated: Gases/vapours, harmful
10.4. Conditions to avoid	No information available.
10.5. Incompatible materials	No information available.
10.6. Hazardous decomposition products	Carbon dioxide (CO ₂), CO

11. Toxicological information

11.1. Information on toxicological effects	<p>Toxicokinetics, metabolism and distribution No information available.</p> <p>Acute toxicity Based on available data, the classification criteria are not met.</p> <p>Irritation and corrosivity Based on available data, the classification criteria are not met.</p> <p>Sensitising effects Based on available data, the classification criteria are not met.</p> <p>Carcinogenic/mutagenic/toxic effects for reproduction Based on available data, the classification criteria are not met.</p> <p>STOT-single exposure Based on available data, the classification criteria are not met.</p> <p>STOT-repeated exposure Based on available data, the classification criteria are not met.</p> <p>Aspiration hazard Based on available data, the classification criteria are not met.</p>
---	---

12. Ecological information

12.1. Toxicity	No information available.
12.2. Persistence and degradability	The product is: Not readily biodegradable (according to OECD criteria)
12.3. Bioaccumulative potential	No information available.
12.4. Mobility in soil	No information available.
12.5. Results of PBT and vPvB assessment	The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
12.6. Other adverse effects	No information available.



13. Disposal considerations

13.1. Waste treatment methods	<p>Advice on disposal Dispose of waste according to applicable legislation.</p> <p>Contaminated packaging Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.</p>
--------------------------------------	--

14. Transport information

Land transport (ADR/RID)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards	ENVIRONMENTALLY HAZARDOUS: no.
14.6. Special precautions for user	No dangerous good in sense of this transport regulation.
14.7. Transport in bulk according to Annex II of Marpol and the IBC Code	No dangerous good in sense of this transport regulation.



15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	National regulatory information Water contaminating class (D): not water contaminating
15.2. Chemical safety assessment	Chemical safety assessments for substances in this mixture were not carried out.

16. Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID:Règlement international conernat le transport des marchandises dangereuses par chemin de fer
(Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Refulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
CAS: Chemical Abstracts Service (division of the American Chemical Society)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures,
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
EC50: Effectice concentration, 50 percent
DNEL: Derived No Effect Level
PNEC: Predicted No Effect Concentration
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.