

SAFETY DATA SHEET

according to Regulation (EU) 2020/878

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Temporary Cavity Filling Material

Revision 13

Revision date 2025-02-14

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	Temporary Cavity Filling Material
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1.2. Relevant identified uses of the substance or mixture and uses advised against

Product Use	[SU22] Professional uses: Public domain (administration, education, entertainment, services, craftsmen);
Restricted use	[SU21] Consumer uses: Private households (= general public = consumers);
Description	Dental product.

1.3. Details of the supplier of the safety data sheet

Company	Centrix Incorporated
Address	770 River Road Shelton, CT 06484 USA
Web	www.centrixdental.com
Telephone	+ 800-235-5862
Fax	
Email	csorders@centrixdental.com
Email address of the competent person	twhite@centrixdental.com

1.4. Emergency telephone number

Emergency telephone number	+ 800-235-5862
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Eye Irrit. 2: H319; Aquatic Chronic 2: H411;
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2.2. Label elements

Hazard pictograms	
Signal Word	Warning
Hazard Statement	Eye Irrit. 2: H319 - Causes serious eye irritation. Aquatic Chronic 2: H411 - Toxic to aquatic life with long lasting effects.

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2.2. Label elements

Precautionary Statement: Prevention	P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	P391 - Collect spillage.

2.3. Other hazards

Other hazards	PBT. vPvB. Not applicable.
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Further information

	Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
Diethylene glycol monoethyl ether acetate		112-15-2	203-940-1		10 - 20%	Eye Irrit. 2: H319;
Zinc oxide	030-013-00-7	1314-13-2	215-222-5	01-2119463881-32	10 - 20%	Aquatic Acute 1: H400; Aquatic Chronic 1: H410;

Further information

	Full text for all Hazard Statements mentioned in this section are displayed in Section 16.
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SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open.
Skin contact	Wash off immediately with plenty of soap and water. Remove contaminated clothing.
Ingestion	Do NOT induce vomiting.

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

Inhalation	May cause irritation to mucous membranes.
Eye contact	May cause irritation to eyes.
Skin contact	May cause irritation to skin.
Ingestion	Ingestion may cause nausea and vomiting.

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

Inhalation	Seek medical attention if irritation or symptoms persist.
Eye contact	Seek medical attention if irritation or symptoms persist.
Skin contact	Seek medical attention if irritation or symptoms persist.
Ingestion	Seek medical attention if irritation or symptoms persist.

General information

	If you feel unwell, seek medical advice (show the label where possible).
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SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2. Special hazards arising from the substance or mixture

	Burning produces irritating, toxic and obnoxious fumes.
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5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area. Wear suitable protective equipment.

6.2. Environmental precautions

Do not allow product to enter drains. Prevent further spillage if safe.

6.3. Methods and material for containment and cleaning up

Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

6.4. Reference to other sections

See Section 13 for disposal information. See Section 8 for exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2. Conditions for safe storage, including any incompatibilities

Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in original container.

7.3. Specific end use(s)

See section 1.2. Relevant identified uses of the substance or mixture and uses advised against for further information.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

Barium Sulphate	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: -
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	WEL 8-hr limit mg/m3 total 10	WEL 15 min limit mg/m3 total -
	inhalable dust:	inhalable dust:
	WEL 8-hr limit mg/m3 total 4	WEL 15 min limit mg/m3 total -
	respirable dust:	respirable dust:
	PNEC Aqua(Fresh):	PNEC Aqua(Marine):
	PNEC Sediment(Fresh):	PNEC Sediment(Marine):
	PNEC Soil:	

8.2. Exposure controls

8.2.1. Appropriate engineering controls 8.2.2. Individual protection measures Eye / face protection	 	
	Ensure adequate ventilation of the working area.	
	Wear chemical protective clothing.	
	Approved safety goggles.	

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8.2. Exposure controls

Skin protection - Handprotection	Chemical resistant gloves.
Respiratory protection	Wear suitable respiratory equipment when necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Paste
Colour	White/Pink
Odour	Mild
Odour threshold	Not applicable.
pH	No data available
Melting point	No data available
Freezing Point	No data available
Initial boiling point	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Vapour pressure	Not applicable.
Relative Vapour Density	Not applicable.
Density / Relative Density	No data available
Fat Solubility	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidising properties	No data available
Solubility	Insoluble in water

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	Not applicable.
Benzene Content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

9.2.1. Information with regard to physical hazard classes

	No data is available on this product.
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9.2.2. Other safety characteristics

	No data is available on this product.
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SECTION 10: Stability and reactivity

10.1. Reactivity

	No data available.
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10.2. Chemical stability

	Stable under normal conditions.
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10.3. Possibility of hazardous reactions

	No data is available on this product.
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10.4. Conditions to avoid

	Heat. Moisture.
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10.5. Incompatible materials

	Strong acids. Strong bases.
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10.6. Hazardous decomposition products

	No data available.
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SECTION 11: Toxicological information

11.1 Information on hazard classes

Acute toxicity	No data available.
Skin corrosion/irritation	May cause irritation to skin.
Serious eye damage/irritation	May cause irritation to eyes.
Respiratory or skin sensitisation	May cause irritation to mucous membranes.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	No carcinogenic effects reported.
Reproductive toxicity	No teratogenic effects reported.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	Irritating to respiratory system.
Repeated or prolonged exposure	Irritating to skin.

11.1.4. Toxicological Information

Barium Sulphate	Oral Rat LD50: >5000 mg/kg bw
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11.2 Information on other hazards

	No data is available on this product.
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SECTION 12: Ecological information

12.2. Persistence and degradability

	No data is available on this product.
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12.3. Bioaccumulative potential

	No data is available on this product.
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Partition coefficient

	Temporary Cavity Filling Material No data available
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12.4. Mobility in soil

	No data is available on this product.
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12.5. Results of PBT and vPvB assessment

	No data is available on this product.
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12.6 Endocrine disrupting properties

	This product does not contain any known or suspected endocrine disruptors.
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12.7 Other adverse effects

	No data is available on this product.
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SECTION 13: Disposal considerations

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13.1. Waste treatment methods

	Dispose of in compliance with all. local and national regulations.
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General information

	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND /OR RELATED RESEARCH(except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.
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Disposal methods

	Do not empty into drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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Disposal of packaging

	Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling.
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SECTION 14: Transport information

Hazard pictograms

	 
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14.1. UN number

	UN3077
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14.2. UN proper shipping name

	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
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14.3. Transport hazard class(es)

ADR/RID	9
Subsidiary risk	-
IMDG	9
Subsidiary risk	-
IATA	9
Subsidiary risk	-

14.4. Packing group

Packing group	III
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14.5. Environmental hazards

Environmental hazards	Yes
Marine pollutant	Yes

ADR/RID

Hazard ID	90
Tunnel Category	(E)

IMDG

EmS Code	F-A S-F
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IATA

Packing Instruction (Cargo)	956
Maximum quantity	400 kg
Packing Instruction (Passenger)	956

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IATA

Maximum quantity	400 kg
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SECTION 15: Regulatory information

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

Regulations	COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
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15.2. Chemical safety assessment

	No data available.
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SECTION 16: Other information

Other information

Revision	This document differs from the previous version in the following areas: 2 - Hazard pictograms.
Text of Hazard Statements in Section 3	Eye Irrit. 2: H319 - Causes serious eye irritation. Aquatic Acute 1: H400 - Very toxic to aquatic life. Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.

Further information

	The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process.
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