

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

Product form : Mixture
Product name : Tempit[®]-E Temporary Filling and Sealing Material with Eugenol

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Use of the substance/mixture : Dental product

1.2.2. Uses advised against

Restrictions on use : For professional use only

1.3. Details of the supplier of the safety data sheet

Centrix, Inc.
770 River Road
Shelton, CT 06484
T (203) 929-5582
csorders@centrixdental.com, www.centrixdental.com

1.4. Emergency telephone number

Emergency number : +1 (800) 235-5862 or +1 (203) 929-5582

Country/Area	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Serious eye damage/eye irritation, Category 2 H319
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H410
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP) :



GHS07

GHS09

Signal word (CLP)

: Warning

Hazard statements (CLP)	: H319 - Causes serious eye irritation. H410 – Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P264 - Wash hands thoroughly after handling. P273 - Avoid release to the environment. P280 - Wear eye protection. P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention. P391 - Collect spillage. P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Barium Sulfate substance with national workplace exposure limit(s) (GB)	CAS-No.: 7727-43-7 EC-No.: 231-784-4 Reach reg. No.: 01-2119491274-35	10-20	Not classified
Diethylene glycol monoethyl ether acetate	CAS-No.: 112-15-2 EC-No.: 203-940-1	10-20	Eye Irrit. 2, H319
Zinc oxide	CAS-No.: 1314-13-2 EC-No.: 215-222-5 EC Index-No.: 030-013-00-7 Reach Reg. No.: 01-2119463881-32	1-10	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Eugenol	CAS-No.: 97-53-0 EC-No.: 202-589-1 Reach Reg. No.: 01-2119971802-33	1-10	Asp. Tox. 1: H304; Skin Sens. 1: H317; Eye Irrit. 2: H319

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Do NOT induce vomiting. Call a poison center or a doctor if you feel unwell.

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

Inhalation	: Dust of the product, if present, may cause respiratory irritation after excessive inhalation exposure.
Skin	: No adverse effects expected under normal conditions of use. Product dust may cause mechanical irritation to the skin and mucous membranes.
Eyes	: May cause moderate irritation to the eyes.

Ingestion	: Ingestion may cause nausea, vomiting and diarrhea.
Chronic symptoms	: None known.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: This product is not classified as flammable or combustible.
Explosion hazard	: Prolonged exposure to fire may cause containers to rupture/explode.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). Sulfur oxides (SO _x). Metal oxides. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Use self-contained breathing apparatus and chemically protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Stop leak if safe to do so. Do not touch or walk on the spilled product. Notify authorities if product enters sewers or public waters.
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6.1.1. For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Avoid contact with eyes, skin and clothing. Avoid breathing dust. Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: Evacuate unnecessary personnel. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Stop leak without risks if possible.
Methods for cleaning up	: Absorb and/or contain spill with inert material, then place in suitable container. Clean contaminated surfaces with an excess of water.
Other information	: Dispose of materials or solid residues at an authorised site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Avoid contact with eyes. Avoid repeated or prolonged skin contact. Wear personal protective equipment. Avoid dust formation. Ensure adequate ventilation. Keep container closed when not in use. Keep away from heat and direct sunlight.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in dry, cool, well-ventilated area. Keep container tightly closed. Store in original container.

7.3. Specific end use(s)

Dental applications.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Barium Sulfate (7727-43-7)	
United Kingdom - Occupational Exposure Limits	
Local name	Barium sulphate
WEL TWA (OEL TWA)	10 mg/m ³ inhalable dust 4 mg/m ³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

8.2.2. Personal protection equipment

Personal protective equipment:

Follow facility requirements on PPE procedures.

8.2.2.1. Eye and face protection

Eye protection:

Wear safety goggles or other eye protection to prevent eye contact. Use eye protection according to EN 166.

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN 13034. EN 14605

Hand protection:

In case of repeated or prolonged contact wear gloves. Wear suitable gloves tested to EN374. Contact your glove supplier for selection assistance.

8.2.2.3. Respiratory protection**Respiratory protection:**

In operations where exposure limits are exceeded or exposure levels are excessive, an approved respirator should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls**Environmental exposure controls:**

Avoid release to the environment.

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

Physical state	: Paste
Colour	: White/Off-white
Appearance	: Paste
Odour	: Characteristic/Mild odor
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not flammable
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Insoluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information**9.2.1. Information with regard to physical hazard classes**

No additional information available

9.2.2. Other safety characteristics

No additional information available

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

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Keep away from heat and direct sunlight. Moisture.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

Barium Sulfate (7727-43-7)

LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 2000 mg/kg

Eugenol (97-53-0)

LD50 oral rat	2300 mg/kg
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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: None known
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11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Toxic to aquatic life with long lasting effects. Avoid release to the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Toxic to aquatic life with long lasting effects.

Eugenol (97-53-0)

Daphnia EC50/48h	1.1300 mg/l
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LC50 – Fish/96h	13.0000 mg/l
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12.2. Persistence and degradability

Tempit[®]-E Temporary Cavity Filling Material

Persistence and degradability	No additional information available.
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12.3. Bioaccumulative potential

Diethylene glycol monoethyl ether Acetate (112-15-2)

Partition coefficient n-octanol/water (Log Pow)	0.32
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose in a safe manner in accordance with local/national regulations.
Sewage disposal recommendations	: Do not dispose of waste into sewer. Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Do not re-use empty containers. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)	Environmentally hazardous substance, solid, n.o.s. (Zinc oxide)
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide), 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide), 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s. (Zinc oxide), 9, III
14.3. Transport hazard class(es)		
9	9	9

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ADR	IMDG	IATA
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 
Tunnel restriction code (ADR)	: -
EAC code	: 2Z

Transport by sea

Special provisions (IMDG)	: 274, 335, 375, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

Air transport

PCA Excepted quantities (IATA)	: E1
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PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

New SDS.

Abbreviations and acronyms:

ACGIH	American Conference of Government Industrial Hygienists
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Tempit[®]-E Temporary Cavity Filling Material

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Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
COD	Chemical oxygen demand (COD)
CSA	Chemical safety assessment
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
ED	Endocrine disruptor
EN	European Standard
EWC	European waste catalogue
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)
MAK	maximum workplace concentration
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
N.O.S.	Not Otherwise Specified
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OSHA	Occupational Safety Health Administration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
PPE	Personal protection equipment
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

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Abbreviations and acronyms:

STP	Sewage treatment plant
TF	Technical function
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
TWA	Time Weighted Average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
UFI	Unique Formula Identifier

Data sources : ECHA (European Chemicals Agency).

Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Eye Irrit. 2	H319	Calculation method
Aquatic Chronic 2	H410	Calculation method

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.