

SAFETY DATA SHEET

according to Regulation (EU) 2015/830

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Temporary Filling Material

Revision 7
Revision date 2020-01-13

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

1.1. Product identifier

| | |
|---------------------|----------------------------|
| Product name | Temporary Filling Material |
|---------------------|----------------------------|

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); [SU20] Health services; |
| 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 | Advanced Healthcare Ltd | |
| Address | Units 2-4 Leavers Estate, Chiddingstone Causeway, Tonbridge, Kent, TN11 8JU, UK | |
| Web | www.ahl.uk.com | W9 Pty Ltd |
| Telephone | +44 (0) 1892 870500 (Use for Emergency also) | Unit 1, 27-29 Salisbury Road |
| Fax | +44 (0)1892 870482 | Hornsby NSW 2077 Australia |
| Email | sales@ahl.uk.com | P (02) 9987 4224 |
| Email address of the competent person | sales@ahl.uk.com | F (02) 9476 6629 |

1.4. Emergency telephone number


| | | |
|-----------------------------------|---|---|
| Emergency telephone number | +44(0)1892870500 (8.00 am - 4.30 pm Mon - Fri) | NSW Poisons Information Centre 13 11 26 |
|-----------------------------------|---|---|

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

| | |
|---|--|
| 2.1.2. Classification - EC 1272/2008 | Repr. 1A: H360Df; Aquatic Chronic 2: H411; |
|---|--|

2.2. Label elements

| | |
|--------------------------|--|
| Hazard pictograms |  |
| Signal Word | Danger |
| Hazard Statement | Repr. 1A: H360Df - May damage the unborn child. Suspected of damaging fertility. 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. |
|----------------------|----------------------------|

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. |
|--|--|

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 |
|-------------------------------------|--------------|-----------|-----------|---------------------------|--------------|--|
| Tetraethylene Glycol Dimethyl Ether | | 143-24-8 | 205-594-7 | 01-2119958965-16 | 10 - 20% | Repr. 1A: H360Df; |
| 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; |

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). |
|--|--|

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--|---|
| | Use extinguishing media appropriate to the surrounding fire conditions. |
|--|---|

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| | Burning produces irritating, toxic and obnoxious fumes. |
|--|---|

5.3. Advice for firefighters

| | |
|--|---|
| | Wear suitable respiratory equipment when necessary. |
|--|---|

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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: |

8.2. Exposure controls



8.2.1. Appropriate engineering controls

Ensure adequate ventilation of the working area.

8.2.2. Individual protection measures

Wear chemical protective clothing.

Eye / face protection

Approved safety goggles.

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

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9.1. Information on basic physical and chemical properties

| | |
|----------------------------------|--------------------|
| Appearance | Paste |
| Colour | White/Pink |
| Odour | Mild |
| 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 |
| 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. |
| Vapour density | Not applicable. |
| Relative density | 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 |

SECTION 10: Stability and reactivity

10.1. Reactivity

| | |
|--|--------------------|
| | No data available. |
|--|--------------------|

10.2. Chemical stability

| | |
|--|---------------------------------|
| | Stable under normal conditions. |
|--|---------------------------------|

10.3. Possibility of hazardous reactions

| | |
|--|---------------------------------------|
| | No data is available on this product. |
|--|---------------------------------------|

10.4. Conditions to avoid

| | |
|--|-----------------|
| | Heat. Moisture. |
|--|-----------------|

10.5. Incompatible materials

| | |
|--|-----------------------------|
| | Strong acids. Strong bases. |
|--|-----------------------------|

10.6. Hazardous decomposition products

| | |
|--|--------------------|
| | No data available. |
|--|--------------------|

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------|--------------------|
| Acute toxicity | No data available. |
|-----------------------|--------------------|

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11.1. Information on toxicological effects

| | |
|-----------------------------------|--|
| 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 | May cause harm to the unborn child. Suspected of damaging fertility. |
| 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 |
|-----------------|-------------------------------|

SECTION 12: Ecological information

12.2. Persistence and degradability

| | |
|--|---------------------------------------|
| | No data is available on this product. |
|--|---------------------------------------|

12.3. Bioaccumulative potential

| | |
|--|---------------------------------------|
| | No data is available on this product. |
|--|---------------------------------------|

Partition coefficient

| | |
|--|--|
| | Temporary Filling Material No data available |
|--|--|

12.4. Mobility in soil

| | |
|--|---------------------------------------|
| | No data is available on this product. |
|--|---------------------------------------|

12.5. Results of PBT and vPvB assessment

| | |
|--|---------------------------------------|
| | No data is available on this product. |
|--|---------------------------------------|

12.6. Other adverse effects

| | |
|--|---|
| | Very toxic to aquatic life with long lasting effects. |
|--|---|

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|--|--|
| | Dispose of in compliance with all. local and national regulations. |
|--|--|

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. |
|--|--|

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. |
|--|--|

Disposal of packaging

| | |
|--|--|
| | Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling. |
|--|--|

SECTION 14: Transport information

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Hazard pictograms

| | |
|--|---|
| |  |
|--|---|

14.1. UN number

| | |
|--|--------|
| | UN3077 |
|--|--------|

14.2. UN proper shipping name

| | |
|--|--|
| | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
|--|--|

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 |
|---------------|-----|

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 |
|----------|---------|

IATA

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

SECTION 15: Regulatory information

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

| | |
|-------------|---|
| Regulations | <p>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.</p> |
|-------------|---|

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15.2. Chemical safety assessment

| | |
|--|--------------------|
| | No data available. |
|--|--------------------|

SECTION 16: Other information

Other information

| | |
|---|---|
| Revision | This document differs from the previous version in the following areas:. 2 - 2.1. Classification of the substance or mixture. 2 - Hazard pictograms. 2 - Precautionary Statement: Prevention. 2 - Precautionary Statement: Response. 2 - Precautionary Statement: Storage. 2 - Precautionary Statement: Disposal. 15 - Hazard Statement. 15 - Safety phrases. |
| Text of Hazard Statements in Section 3 | Repr. 1A: H360Df - May damage the unborn child. Suspected of damaging fertility. 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. |
|--|--|