

SAFETY DATA SHEET

PALFIQUE ESTELITE PASTE

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

1.1. Product identifier

Product name PALFIQUE ESTELITE PASTE

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

Identified uses 【Medical device】 Resin-based dental restorative material. For dental professionals only.

Uses Not Recommended Use only for intended applications.

1.3. Details of the supplier of the safety data sheet

Supplier Tokuyama Dental Italy S.r.l.
Via Chizzalunga, 1,
36066 Sandrigo, Vicenza, Italy
TEL: +39-0444-659650
FAX: +39-0444-750345

Contact person <http://www.tokuyama-dental.com/tdc/contact.html>

Manufacturer Tokuyama Dental Corporation
38-9, Taitou 1-chome, Taitou-ku, Tokyo
110-0016, Japan
TEL: +81-3-3835-2261
FAX: +81-3-3835-2265

1.4. Emergency telephone number

Emergency telephone Regional Medicines and Poisons Information Centre NI,
Pharmacy Department
Royal Hospital Suite, Grosvenor Road, Belfast
Emergency telephone: 844 892 0111
Telephone: +44 28 90 63 2032
Fax: +44 28 90 24 8030
E-mail address: nirdic.nirdic@belfasttrust.hscni.net

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Skin Sens. 1 - H317

Environmental hazards Not Classified

2.2. Label elements

Pictogram



Signal word Warning

Hazard statements H317 May cause an allergic skin reaction.

Precautionary statements P261 Avoid breathing vapours.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P501 Dispose of contents/ container in accordance with local regulations.

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Contains (1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE, 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE, MEQUINOL

Supplementary precautionary statements P272 Contaminated work clothing should not be allowed out of the workplace.
P321 Specific treatment (see medical advice on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

2.3. Other hazards This product does not contain any substances classified as PBT or vPvB.
Endocrine disrupting properties: Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

| | |
|--|-----------------|
| COMPOSITE FILLER | 45-55% |
| CAS number: - EC number.: - | |
| Classification : Substance not classified as hazardous | |
| SILICA-ZIRCONIA FILLER | 25-35% |
| CAS number: - EC number / REACH Registration No.: 910-388-1 / 01-2119860534-36-0000 | |
| Classification : Substance not classified as hazardous | |
| (1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY (2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE | 5-15% |
| CAS number: 1565-94-2 EC number: 216-367-7 | |
| Classification : Skin Sens.1 - H317, Aquatic Chronic 3 - H412 | |
| 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE | 5-10% |
| CAS number: 109-16-0 EC number: 203-652-6 | |
| Classification : Skin Irrit.2 - H315, Eye Irrit.2 - H319, Skin Sens.1 - H317 | |
| SILICA-TITANIA FILLER | 1-5% |
| CAS number: - EC number.: - | |
| Classification : Substance not classified as hazardous | |
| MEQUINOL | <0.1% |
| CAS number: 150-76-5 EC number.: 205-769-8 | |
| Classification : Acute Tox. 4 H302, Skin Sens. 1 H317, Eye Irrit. 2 H319 | |
| TITANIUM DIOXIDE | <0.1% |
| CAS number: 13463-67-7 EC number.:236-675-5 | |
| Classification : Acute Tox. 4 - H332, Carc. 2 - H351 | |
| 2,6-DI-tert-BUTYL-p-CRESOL | <0.1% |
| CAS number: 128-37-0 EC number.:204-881-4 | |
| Classification : Aquatic Chronic 1 - H410 M factor (Chronic) = 1 | |

The full text for all hazard statements is displayed in Section 16.

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SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|----------------------------|--|
| General information | Move affected person to fresh air at once. Get medical attention if any discomfort continues. |
| Inhalation | Move affected person to fresh air at once. |
| Ingestion | Try to induce vomiting. Get medical attention if any discomfort continues. |
| Skin contact | Wash skin thoroughly with soap and water. |
| Eye contact | Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing. |

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

| | |
|---------------------|----------------|
| Skin contact | Allergic rash. |
|---------------------|----------------|

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

| | |
|-----------------------------|------------------------------|
| Notes for the doctor | No specific recommendations. |
|-----------------------------|------------------------------|

SECTION 5: Firefighting measures

5.1. Extinguishing media

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| Suitable extinguishing media | Extinguish with the following media: Foam. Carbon dioxide or dry powder. |
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5.2. Special hazards arising from the substance or mixture

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|--------------------------------------|--|
| Specific hazards | Irritating gases or vapours. |
| Hazardous combustion products | No known hazardous decomposition products. |

5.3. Advice for firefighters

| | |
|--|--|
| Protective actions during firefighting | Avoid breathing fire gases or vapours. |
| Special protective equipment for firefighters | Wear chemical protective suit. |

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions No specific recommendations.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation. Absorb in vermiculite, dry sand or earth and place into containers.

6.4. Reference to other sections

Reference to other sections For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions All handling should only take place in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in a cool, dark place (0-25°C, 32-77°F). Keep away from heat, direct sunlight, sparks and open flames.

Storage class Chemical storage.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

2,6-DI-tert-BUTYL-p-CRESOL

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³

WEL = Workplace Exposure Limit

8.2. Exposure controls

Appropriate engineering controls Provide adequate general and local exhaust ventilation.

Eye/face protection The following protection should be worn: Chemical splash goggles.

Hand protection Wear protective gloves.

Other skin and body protection Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures Do not smoke in work area. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

Respiratory protection No specific recommendations. Respiratory protection must be used if the airborne contamination exceeds the recommended occupational exposure limit.

SECTION 9: Physical and Chemical Properties

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9.1. Information on basic physical and chemical properties

| | |
|--|-------------------------------|
| Appearance | Paste |
| Colour | Yellow-white |
| Odour | Not available. |
| Odour threshold | Not available. |
| pH | pH (concentrated solution): 7 |
| Melting point | Not available. |
| Initial boiling point and range | Not available. |
| Flash point | Not available. |
| Evaporation rate | Not available. |
| Evaporation factor | Not available. |
| Upper/lower flammability or explosive limits | Not applicable. |
| Other flammability | Not available. |
| Vapour pressure | Not available. |
| Vapour density | Not available. |
| Relative density | 1.9 |
| Solubility(ies) | Not available. |
| Partition coefficient | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition Temperature | Not available. |
| Viscosity | Not available. |
| Explosive properties | Not explosive. |
| Oxidising properties | Not available. |

9.2. Other information

| | |
|-------------------|----------------|
| Other information | Not available. |
|-------------------|----------------|

SECTION 10: Stability and reactivity

10.1. Reactivity

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|------------|-----------------|
| Reactivity | May polymerise. |
|------------|-----------------|

10.2. Chemical stability

| | |
|-----------|---|
| Stability | Stable at normal ambient temperatures and when used as recommended. |
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10.3. Possibility of hazardous reactions

| | |
|------------------------------------|----------------------------|
| Possibility of hazardous reactions | Not known. May polymerise. |
|------------------------------------|----------------------------|

10.4. Conditions to avoid

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|---------------------|--|
| Conditions to avoid | Keep away from heat, sparks and open flame. Protect against direct sunlight. |
|---------------------|--|

10.5. Incompatible materials

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Materials to avoid Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity - Ingestion

Calculation method : Not classified.

Acute toxicity - Skin Contact

Calculation method : Not classified. No data.

Acute toxicity - Inhalation

Calculation method : Not classified. No data.

Skin corrosion/irritation

Calculation method : Not classified. Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Calculation method : Not classified. Based on available data, the classification criteria are not met.

Skin sensitization

Calculation method : May cause an allergic skin reaction.

Respiratory sensitization

Calculation method : Not classified.

Germ cell mutagenicity

Calculation method : Not classified.

Carcinogenicity

Calculation method : Not classified.

Reproductive toxicity

Calculation method : Not classified.

Lactation

Calculation method : Not classified.

STOT - single exposure

Calculation method : Not classified. Based on available data, the classification criteria are not met.

STOT - repeated exposure

Calculation method : Not classified. Based on available data, the classification criteria are not met.

Aspiration hazard Not classified.

Calculation method : Not classified. Not applicable.

11.2 Other information

Route(s) of entry Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2 .

Endocrine disrupting properties: Not known.

SECTION 12: Ecological Information

12.1 Toxicity

Toxicity - Aquatic invertebrates Not classified.

Toxicity - Fish Not classified.

Toxicity - Algae Not classified.

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Toxicity - Sediment Compartment Not classified.

Toxicity - Terrestrial Compartment Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6 Endocrine disrupting properties

Not known.

12.7 Other adverse effects

Not known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/ regional/ national/ international regulations.
Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information

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

EU legislation (EC) No 1907/2006 (REACH).
(EC) No 1272/2008 (CLP).
(EU) No 2015/830.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008 Skin Sens. 1 - H317: Calculation method.

Training advice Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

Revision comments

Revision date 15/12/2022

Revision 5

Hazard statements in full
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

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