

SAFETY DATA SHEET

OMNICHROMA

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

1.1. Product identifier

Product name OMNICHROMA

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

Identified uses Resin-based Dental Restorative Material. For dental professionals only.

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 dust.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/ container in accordance with local regulations.

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Contains 7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE, 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE

Supplementary precautionary statements P272 Contaminated work clothing should not be allowed out of the workplace.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see medical advice on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/ attention.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE	10-30%
CAS number: 72869-86-4 EC number: 276-957-5	
Classification Skin Sens. 1 - H317	
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	1-5%
CAS number: 109-16-0 EC number: 203-652-6	
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317	
2,6-DI-tert-BUTYL-p-CRESOL	<1%
CAS number: 128-37-0 EC number: 204-881-4 M factor (Chronic) = 1	
Classification Aquatic Chronic 1 - H410	
DL-BORNANE-2,3-DIONE	<1%
CAS number: 10373-78-1 EC number: 233-814-1	
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 3 - H335	

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MEQUINOL	<1%
CAS number: 150-76-5	EC number: 205-769-8
Classification Acute Tox. 4 - H302 Eye Irrit. 2 - H319 Skin Sens. 1 - H317	

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

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	Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. 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.
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4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	No specific recommendations.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Specific hazards	When heated and in case of fire, irritating vapours/gases may be formed.
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Hazardous combustion products	No known hazardous decomposition products.
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5.3. Advice for firefighters

Protective actions during firefighting	Avoid breathing fire gases or vapours.
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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.
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6.2. Environmental precautions

Environmental precautions	No specific recommendations.
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6.3. Methods and material for containment and cleaning up

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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 and well-ventilated place. Store at temperatures between 0°C/25°F and 32°C/77°F. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid exposure to high temperatures or direct sunlight.

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. Personal, workplace environment or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Personal protective equipment should only be used if worker exposure cannot be controlled adequately by the engineering control measures.

Personal protection Wear appropriate clothing to prevent any possibility of skin contact.

Eye/face protection Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Personal protective equipment for eye and face protection should comply with European Standard EN166. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses.

Hand protection Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacture, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374. Considering the data specified by the glove manufacturer, check during use that the gloves are retaining their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended.

Other skin and body protection Appropriate footwear and additional protective clothing complying with an approved standard should be worn if a risk assessment indicates skin contamination is possible.

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Hygiene measures	Provide eyewash station and safety shower. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Clean equipment and the work area every day. Good personal hygiene procedures should be implemented. Wash at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Preventive industrial medical examinations should be carried out. Warn cleaning personnel of any hazardous properties of the product.
Respiratory protection	Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges should comply with European Standard EN14387. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.
Environmental exposure controls	Keep container tightly sealed when not in use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Paste
Colour	White to slightly yellowish
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.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not applicable.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1.8
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.

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Oxidising properties Not available.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity May polymerise. See the other subsections of this section for further details.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Not known.

10.4. Conditions to avoid

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

10.5. Incompatible materials

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

Routes of exposure Skin , Eyes , Ingestion , Inhalation , Health effects: See section 4.2.

Acute toxicity - oral

Notes (oral LD₅₀) Not available.

Acute toxicity - dermal

Notes (dermal LD₅₀) Not available.

Acute toxicity - inhalation

Notes (inhalation LC₅₀) Not available.

Skin corrosion/irritation

Skin corrosion/irritation Not available.

Animal data

Not available.

Serious eye damage/irritation

Serious eye damage/irritation Not available.

Respiratory sensitisation

Respiratory sensitisation Not available.

Skin sensitisation

Skin sensitisation Not available.

Germ cell mutagenicity

Genotoxicity - in vitro Not available.

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Genotoxicity - in vivo	Not available.
<u>Carcinogenicity</u>	
Carcinogenicity	Not available.
IARC carcinogenicity	Some of the ingredients are listed or exempt.
<u>Reproductive toxicity</u>	
Reproductive toxicity - fertility	Not available.
Reproductive toxicity - development	Not available.
<u>Specific target organ toxicity - single exposure</u>	
STOT - single exposure	Not available.
<u>Specific target organ toxicity - repeated exposure</u>	
STOT - repeated exposure	Not available.
<u>Aspiration hazard</u>	
Aspiration hazard	Not available.
<u>Toxicological information on ingredients.</u>	

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

Carcinogenicity

IARC carcinogenicity	IARC Group 3 Not classifiable as to its carcinogenicity to humans.
NTP carcinogenicity	Reasonably anticipated to be a human carcinogen.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity	Not available.
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Ecological information on ingredients.

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

Chronic aquatic toxicity

M factor (Chronic)	1
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12.2. Persistence and degradability

Persistence and degradability	No data available.
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12.3. Bioaccumulative potential

Bioaccumulative potential	No data available on bioaccumulation.
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Partition coefficient	Not available.
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12.4. Mobility in soil

Mobility	No information available.
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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	This product does not contain any substances classified as PBT or vPvB.
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12.6. Other adverse effects

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Other adverse effects Not known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

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)

No transport warning sign required.

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

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.
Directive 93/42/EEC.

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.

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Revision comments	This is the first issue.
Revision date	15/09/2018
Revision	1
Hazard statements in full	H302 Harmful if swallowed. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H410 Very toxic to aquatic life with long lasting effects.