

**OMNICHROMA**

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) &amp; 2020/878

**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 Use(s) **[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**

## Manufacturer

Company Identification Tokuyama Dental Corporation  
Address of Manufacturer 38-9, Taitou 1-chome, Taitou-ku, Tokyo, Japan

Postal code 110-0016

Telephone: +81-3-3835-2261

Fax +81-3-3835-2265

## Supplier

Company Identification Tokuyama Dental Italy S.r.l.  
Address of Supplier Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy

Telephone: +39-0444-659650

Fax +39-0444-750345

## E-mail

<http://www.tokuyama-dental.com/tdc/contact.html>**1.4 Emergency telephone number**

Emergency Phone No. (UK)844 892 0111

Contact 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](mailto:nirdic.nirdic@belfasttrust.hscni.net)

## National response center

Contact NHS Direct

Emergency Phone No. +44 111

**SECTION 2: HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**

Regulation (EC) No. 1272/2008 (CLP) Skin Sens. 1 :May cause an allergic skin reaction.

**2.2 Label elements**According to Regulation (EC) No. 1272/2008 (CLP)  
Product Name OMNICHROMA

## Hazard Pictogram(s)



## Signal Word(s)

GHS07

Warning

## Hazard Statement(s)

H317: May cause an allergic skin reaction.

## Precautionary Statement(s)

P261 Avoid breathing vapours.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/ container in accordance with local regulations

**2.3 Other hazards**None known. This product does not contain any substances classified as PBT or vPvB.  
Endocrine disrupting properties: Not known.**2.4 Additional Information**

## 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,

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For full text of H/P Statements see section 16.

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****3.1 Substances**

Not applicable.

**3.2 Mixtures**

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	% W/W	Hazard Statement(s)	Hazard Pictogram(s)
COMPOSITE FILLER	-	-	40-60	Not Classified	-
REACTION MASS OF SILICON DIOXIDE AND ZIRCONIUM DIOXIDE	-	910-388-1 01-2119860534-36-0000	30-40	Not Classified	-
7,7,9(OR 7,9,9)-TRIMETHYL-4,13- DIOXO-3,14-DIOXA-5,12- DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE	72869-86-4	276-957-5	10-25	Skin Sens. 1 H317	GHS07
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	109-16-0	203-652-6	1-10	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07
MEQUINOL	150-76-5	205-769-8	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0	204-881-4	<0.1	Aquatic Chronic 1 H410	GHS09

HAZARDOUS INGREDIENT(S)	CAS No.	Specific concentration limits	M-factor, M factor (Chronic) =1	ATE
MEQUINOL	150-76-5	-	-	Acute Tox. 4 (H302) : 500
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0	-	M factor (Chronic) =1	-

Contains no non-classified vPvB substances.

Contains no non-classified substances with a Union workplace exposure limit.

For full text of H/P Statements see section 16.

**SECTION 4: FIRST AID MEASURES****4.1 Description of first aid measures**

General	Move affected person to fresh air at once. Get medical attention if any discomfort continues
Inhalation	Move affected person to fresh air at once. 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.
Ingestion	Try to induce vomiting. Get medical attention if any discomfort continues.

**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**

No specific recommendations.

**SECTION 5: FIREFIGHTING MEASURES****5.1 Extinguishing media**

Suitable Extinguishing media Extinguish with the following media: Foam. Carbon dioxide or dry powder.

Unsuitable extinguishing media Not known.

**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.

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.

**OMNICHROMA****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**

Do not allow to enter drains, sewers or watercourses. This material and its container must be disposed of in a safe way.

**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**

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/32 °F and 25°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.

Storage temperature                              Storage temperature (°C): 0-25°C .

Storage life    Stable under normal conditions.

Incompatible materials                              Incompatible with organic peroxides. Oxidizing agents, Acids, Alkalis .

**7.3 Specific end use(s)**

【Medical Device】 Resin-based Dental Restorative Material. For dental professionals only.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Control parameters****8.1.1 Occupational Exposure Limits**



Occupational Exposure Limits						
SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m <sup>3</sup> )	STEL (ppm)	STEL (mg/m <sup>3</sup> )	Note
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0		10			WEL
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0		10			Comp,

Region	Source
EU	EU Occupational Exposure Limits
United Kingdom	UK Workplace Exposure Limits EH40/2005 (Fourth edition, published 2020)
Remark	Notes
IOELV	Indicative Occupational Exposure Limit Values.
WELL	Workplace Exposure Limit



**8.2 Exposure controls**

8.2.1. 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.

**8.2.2. Personal protection equipment**

	Eye 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.
	Skin protection	Wear appropriate clothing to prevent any possibility of skin contact. 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/manufacturer, 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

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	their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended. Appropriate footwear and additional protective clothing complying with an approved standard should be worn if a risk assessment indicates skin contamination is possible.
	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.
	Thermal hazards None known.
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.

## 8.2.3. Environmental Exposure Controls

Avoid release to the environment. 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	Technical impossibility to obtain the data.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash Point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Density (g/ml)	Not available.
Relative density	1.8
Solubility(ies)	Solubility (Water) : Not available. Solubility (Other) : Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature (°C)	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

**9.2 Other information**

Not available.

**SECTION 10: STABILITY AND REACTIVITY****10.1 Reactivity**

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

**10.2 Chemical Stability**

Stable at normal ambient temperatures and when used as recommended

**OMNICHROMA****10.3 Possibility of hazardous reactions**

Not known.

**10.4 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**

Combustion or thermal decomposition may evolve toxic vapours.

Toxic gases/vapours (Carbon monoxide, Carbon dioxide)

**SECTION 11: TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects**

Acute toxicity - Ingestion

Not classified.

Acute toxicity - Skin Contact

Not classified.

Acute toxicity - Inhalation

Not classified.

Skin corrosion/irritation

Not classified.

Serious eye damage/irritation

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

Skin sensitization data

Calculation method : May cause an allergic skin reaction.

Respiratory sensitization data

Not classified.

Germ cell mutagenicity

Not classified.

Carcinogenicity

Not classified.

2,6-DI-tert-BUTYL-p-CRESOL (CAS No. 128-37-0)

IARC carcinogenicity : IARC Group 3

Not classifiable as to its carcinogenicity to humans.

NTP carcinogenicity : Male : rat-negative, mice-negative

Female : rat-negative, mice-negative

OSHA Carcinogenicity Not listed.

Reproductive toxicity

Not classified.

Lactation

Not classified.

STOT - single exposure

Not classified.

STOT - repeated exposure

Not classified.

Aspiration hazard

Not classified.

**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 available.

Toxicity - Fish

Not available.

Toxicity - Algae

Not available.

Toxicity - Sediment Compartment

Not available.

Toxicity - Terrestrial Compartment

Not available.

**12.2 Persistence and degradability**

No data available,.

**12.3 Bioaccumulative potential**

Bioaccumulative potential

No data available on bioaccumulation.

Partition coefficient

Not available.

**12.4 Mobility in soil**

No information available.

**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**

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/

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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**

<b>General</b>	The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).
<b>14.1 UN number</b>	Not applicable.
<b>14.2 UN proper shipping name</b>	Not applicable.
<b>14.3 Transport hazard class(es)</b>	No transport warning sign required.
<b>14.4 Packing group</b>	Not applicable.
<b>14.5 Environmental hazards</b>	No.
No transport warning sign required.	
<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.

**SECTION 15: REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation	Not listed
REACH: ANNEX XIV list of substances subject to authorisation	Not listed
REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not listed
Community Rolling Action Plan (CoRAP)	2,6-DI-tert-BUTYL-p-CRESOL (128-37-0), 2-(2H-BENZOTRIAZOL-2-YL)-p-CRESOL (2440-22-4)
Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants	Not listed
Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer	Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed
Directive 93/42/EEC	This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the product is classified and labelled according to the CLP regulation.

**National regulations**

Other Not known.

**15.2 Chemical Safety Assessment**

A REACH chemical safety assessment has not been carried out.

**SECTION 16: OTHER INFORMATION**

The following sections contain revisions or new statements:

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Training advice	Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.
Date of First Issue	15-09-2018
Date of Revision	15-12-2022
Revision ( EU )	2

**LEGEND**

Hazard Pictogram(s)



Hazard classification	<p>GHS07  GHS08: GHS: Health hazard  GHS09: GHS: Environment</p> <p>Acute Tox. 4 : Acute toxicity, Category 4  Skin Irrit. 2 : Skin corrosion/irritation, Category 2  Skin Sens. 1 : Skin sensitization, Category 1  Eye Irrit. 2 : Serious eye damage/irritation, Category 2  STOT SE 3 : Specific target organ toxicity — single exposure, Category 3  Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1</p>
Hazard Statement(s)	<p>H302: Harmful if swallowed.  H315: Causes skin irritation.  H317: May cause an allergic skin reaction.  H319: Causes serious eye irritation.  H332 Harmful if inhaled.  H410: Very toxic to aquatic life with long lasting effects.</p>
Precautionary Statement(s)	<p>P261 Avoid breathing dust.  P272 Contaminated work clothing should not be allowed out of the workplace.  P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  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.  P362+P364 Take off contaminated clothing and wash it before reuse.  P501 Dispose of contents/ container in accordance with local regulations.</p>
Acronyms	<p>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  CAS : Chemical Abstracts Service  CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures  DNEL : Derived No Effect Level  EC : European Community  EINECS : European Inventory of Existing Commercial Chemical Substances  IATA : International Air Transport Association  IBC : Intermediate Bulk Container  ICAO : International Civil Aviation Organization  IMDG : International Maritime Dangerous Goods  LTEL : Long term exposure limit  PBT : Persistent, Bioaccumulative and Toxic  PNEC : Predicted No Effect Concentration  REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals  RID : Regulations concerning the International Carriage of Dangerous Goods by Rail  STEL : Short term exposure limit  STOT : Specific Target Organ Toxicity  UN : United Nations  vPvB : very Persistent and very Bioaccumulative  WEL : Workplace Exposure Limit</p>
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