

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

Tokuyama Dental Corporation

Company Identification

38-9, Taitou 1-chome, Taitou-ku, Tokyo, Japan

Address of Manufacturer

110-0016

Postal code

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 Sandriga, 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

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)

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Hazard Pictogram(s)



GHS07

Warning

H317: May cause an allergic skin reaction.

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,	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.

#### 4.3 Indication of any immediate medical attention and special treatment

## 5.1 Extinguishing media

**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

<b>3.3 Advice for firefighters</b>	Avoid breathing fire gases or vapours. Wear chemical protective suit.
Protective actions during Firefighting Special protective equipment for firefighters	



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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 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.
	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. <u>2,6-Di-tert-BUTYL-p-CRESOL (CAS No. 128-37-0)</u> 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.
<b>11.2 Other information</b>	
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 potentia	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 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.

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**LEGEND**

Hazard Pictogram(s)



GHS07

GHS08: GHS: Health hazard

GHS09: GHS: Environment

Hazard classification 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  
 H302: Harmful if swallowed.

Hazard Statement(s) 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.

Precautionary Statement(s) 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).

Acronyms 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.  
 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

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