

**OMNICHROMA FLOW****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1 Product identifier**

Product Name OMNICHROMA FLOW

**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.

**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  
E-mail <http://www.tokuyama-dental.com/tdc/contact.html>

**Supplier**

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

## OMNICHROMA FLOW

Hazard Pictogram(s)



GHS07

Signal Word(s)

Warning

Hazard Statement(s)

H317: May cause an allergic skin reaction.

Precautionary Statement(s)

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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

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 in accordance with local, state or national legislation.

**2.3 Other hazards**

None known. This product does not contain any substances classified as PBT or vPvB.

**2.4 Additional Information**

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate.

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	—	—	30-50	Substance not classified as hazardous	none
SILICA-ZIRCONIA FILLER	—	910-388-1 / 01-2119860534-36-0000	20-40	Substance not classified as hazardous	none
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	15-25	Skin Sens. 1 H317	GHS07
NONAMETHYLENDIOL DIMETHACRYLATE	65833-30-9	835-614-5	5-15	Substance not classified as hazardous	none
SILICON DIOXIDE	112945-52-5	601-216-3	1-10	Substance not classified as hazardous	none
dl-BORNANE-2,3-DIONE *	10373-78-1	233-814-1	<0.1	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335	GHS07
MEQUINOL *	150-76-5	205-769-8	<0.1	Acute Tox. 4 H302	GHS07

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				Skin Sens. 1 H317	
				Eye Irrit. 2 H319	
2,6-DI-tert-BUTYL-p-CRESOL *	128-37-0	204-881-4	<0.1	Aquatic Chronic 1 H410	GHS09

\*: Voluntary disclosure.

## SECTION 4: FIRST AID MEASURES

## 4.1 Description of first aid measures

General	Description of first aid measures : Rescuers should take suitable precautions to avoid becoming casualties themselves. Remove to fresh air immediately. If signs/symptoms continue, get medical attention.
Inhalation	Remove to fresh air immediately. Get medical advice/attention if you feel unwell.
Skin Contact	Wash affected area with plenty of soap and water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention. Special treatment : Observe directions on label and instructions for use.
Eye Contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Try to induce vomiting. If signs/symptoms continue, get medical attention.

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

May cause an allergic skin reaction.

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

No specific recommendations. Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

## 5.1 Extinguishing media

Suitable Extinguishing media Foam, Carbon dioxide, Dry powder, Water spray .

Unsuitable extinguishing media None.

## 5.2 Special hazards arising from the substance or mixture

Combustion or thermal decomposition may evolve toxic vapours. Toxic gases/vapours (Carbon monoxide, Carbon dioxide)

## 5.3 Advice for firefighters

Wear a Heat Protective Suit. As appropriate for surrounding fire. Avoid breathing gas.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

## 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing as per section 8. Provide adequate ventilation.

## 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

Collect spillage. Place in sealable container.

## 6.4 Reference to other sections

See Also Section 8, 13.

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## SECTION 7: HANDLING AND STORAGE

## 7.1 Precautions for safe handling

Wear protective clothing as per section 8. Use only in well-ventilated areas. Avoid breathing vapours. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke during work. Wash hands and exposed skin thoroughly after handling. Take off contaminated clothing and wash it before reuse.

## 7.2 Conditions for safe storage, including any incompatibilities

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from direct sunlight. Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up. Store in dry place.

Storage temperature (°C)

0-25°C .

Storage life

Stable under normal conditions.

Incompatible materials

Strong oxidising agents.

## 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			
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
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## 8.2 Exposure controls

8.2.1. Appropriate engineering controls Ensure adequate ventilation. A washing facility/water for eye and skin cleaning purposes should be present.

## 8.2.2. Personal protection equipment

	Eye Protection	Wear eye protection with side protection (EN166).
	Skin protection	Wear protective clothing and gloves: Impervious gloves (EN 374). Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. Gloves should be changed regularly to avoid permeation problems. Wear solvent-resistant apron and boots.

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	Respiratory protection	Normally no personal respiratory protection is necessary. Respiratory protection may be required under exceptional circumstances when excessive air contamination exists.
	Thermal hazards	None known.

8.2.3. Environmental Exposure Controls Avoid release to the environment.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on basic physical and chemical properties

Appearance	Solid. paste. Colour : White - Slightly Yellowish
Odour	Odourless
Odour threshold	Not known.
pH	Not known.
Melting point/freezing point	Not applicable
Initial boiling point and boiling range	Not applicable.
Flash Point	Not applicable.
Evaporation rate	Not known.
Flammability (solid, gas)	Not known.
Upper/lower flammability or explosive limits	Not known.
Vapour pressure	Not known.
Vapour density	Not known.
Density (g/ml)	Not known.
Relative density	1.7
Solubility(ies)	Solubility (Water) : Not known. Solubility (Other) : Not known.
Partition coefficient: n-octanol/water	Not known.
Auto-ignition temperature	Not known.
Decomposition Temperature (°C)	Not known.
Viscosity	Not known.
Explosive properties	Not known.
Oxidising properties	Not known.

## 9.2 Other information

None.

## SECTION 10: STABILITY AND REACTIVITY

## 10.1 Reactivity

None anticipated.

## 10.2 Chemical Stability

Stable under normal conditions.

## 10.3 Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

**OMNICHROMA FLOW****10.4 Conditions to avoid**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.  
No smoking. Protect from sunlight.

**10.5 Incompatible materials**

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. Calculated acute toxicity estimate (ATE) Calc ATE – 555556
Acute toxicity - Skin Contact	Not classified.
Acute toxicity - Inhalation	Not classified.
Skin corrosion/irritation	Not classified. Based on available data, the classification criteria are not met.
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</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
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.

**SECTION 12: ECOLOGICAL INFORMATION****12.1 Toxicity**

Toxicity - Aquatic invertebrates	Not classified.
Toxicity - Fish	Not classified.
Toxicity - Algae	Not classified.
Toxicity - Sediment Compartment	Not classified.
Toxicity - Terrestrial Compartment	Not classified.

**12.2 Persistence and degradability**

Not known.

**12.3 Bioaccumulative potential**

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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 Other adverse effects**

Not known.

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods**

Dispose of contents in accordance with local, state or national legislation. Normal disposal is via incineration operated by an accredited disposal contractor. Send to a licensed recycler, reclaimer or incinerator. Dispose at suitable refuse site.

**13.2 Additional Information**

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

**SECTION 14: TRANSPORT INFORMATION**

Not classified as hazardous for transport.

**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**

Not classified as a Marine Pollutant.

**14.6 Special precautions for user**

Not known

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not known

**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,	Not listed

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mixtures and articles	
Community Rolling Action Plan (CoRAP)	silicon dioxide (7631-86-9), 2,6-di-tert-butyl-p-cresol (128-37-0)
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: This is the first issue.

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

Date of First Issue 01-11-2020

Date of Revision 01-11-2020

Revision\_(UK) 1

**LEGEND**

Hazard Pictogram(s)



GHS07

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



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Hazard Statement(s)	<p>H302: Harmful if swallowed.</p> <p>H315: Causes skin irritation.</p> <p>H317: May cause an allergic skin reaction.</p> <p>H319: Causes serious eye irritation.</p> <p>H335: May cause respiratory irritation.</p> <p>H410: Very toxic to aquatic life with long lasting effects.</p>
Precautionary Statement(s)	<p>P261: Avoid breathing dust/fume/gas/mist/vapours/spray.</p> <p>P272: Contaminated work clothing should not be allowed out of the workplace.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P302+P352: IF ON SKIN: Wash with plenty of water.</p> <p>P321: Specific treatment (see Medical Advice on this label).</p> <p>P333+P313: If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P362+P364: Take off contaminated clothing and wash it before reuse.</p> <p>P501: Dispose of contents in accordance with local, state or national legislation.</p>
Acronyms	<p>CAS : Chemical Abstracts Service</p> <p>CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures</p> <p>DNEL : Derived No Effect Level</p> <p>EC : European Community</p> <p>EINECS : European Inventory of Existing Commercial Chemical Substances</p> <p>LTEL : Long term exposure limit</p> <p>PBT : Persistent, Bioaccumulative and Toxic</p> <p>PNEC : Predicted No Effect Concentration</p> <p>REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals</p> <p>STEL : Short term exposure limit</p> <p>STOT : Specific Target Organ Toxicity</p> <p>vPvB : very Persistent and very Bioaccumulative</p> <p>IARC : International Agency for Research on Cancer</p> <p>ACGIH : American Conference of Governmental Industrial Hygienists</p> <p>NTP : National Toxicology Program</p>
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