

**OMNICHROMA FLOW**

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 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.

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  
 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**

Product Name According to Regulation (EC) No. 1272/2008 (CLP)  
 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**

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-

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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 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

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**

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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.

**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. 0-25°C .

Storage temperature (°C)

Storage life

Incompatible materials

Stable under normal conditions.

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



**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). The following protection should be worn: Chemical splash goggles.
	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. Keep container tightly sealed when not in use

**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	Technical impossibility to obtain the data.
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**

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

**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.

Calculated acute toxicity estimate (ATE) Calc ATE – 555556

Acute toxicity - Skin Contact

Not classified.

Acute toxicity - Inhalation

Not classified.

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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. 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.
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**

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****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

**OMNICHROMA FLOW****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, 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:

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

15-12-2022

Revision\_(UK)

2

**LEGEND**

Hazard Pictogram(s)



GHS07

Hazard classification

GHS09: GHS: Environment

Acute Tox. 4 : Acute toxicity, Category 4

Skin Irrit. 2 : Skin corrosion/irritation, Category 2

Skin Sens. 1 : Skin sensitization, Category 1

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Hazard Statement(s)	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. 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.
Precautionary Statement(s)	P261: Avoid breathing dust/fume/gas/mist/vapours/spray. 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 in accordance with local, state or national legislation.
Acronyms	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 LTEL : Long term exposure limit PBT : Persistent, Bioaccumulative and Toxic PNEC : Predicted No Effect Concentration REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals STEL : Short term exposure limit STOT : Specific Target Organ Toxicity vPvB : very Persistent and very Bioaccumulative IARC : International Agency for Research on Cancer ACGIH : American Conference of Governmental Industrial Hygienists NTP : National Toxicology Program
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