

OMNICHROMA FLOW

Date of Issue :

01-11-2020

Date of Revision :

15-12-2022

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 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 againstIdentified 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

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

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-

OMNICHROMA FLOW

Date of Issue :

01-11-2020

Date of Revision :

15-12-2022

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

OMNICHROMA FLOW

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.

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 ³)	STEL (ppm)	STEL (mg/m ³)	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.

OMNICHROMA FLOW

	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 productsCombustion 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.

OMNICHROMA FLOWDate of Issue :
01-11-2020Date of Revision :
15-12-2022

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.
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 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 FLOWDate of Issue :
01-11-2020Date of Revision :
15-12-2022**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

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

OMNICHROMA FLOWDate of Issue :
01-11-2020Date of Revision :
15-12-2022

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

Hazard Statement(s)
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

Disclaimers
The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be relied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such.