

OMNICHROMA FLOW

ACCORDING TO HAZARDOUS PRODUCTS REGULATIONS (HPR)

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 America, Inc.
 Address of Supplier 740 Garden View Ct., Suite 200 Encinitas, CA 92024 U.S.A.
 Telephone: +1-760-942-7211
 Fax +1-760-942-7212
 E-mail <http://www.tokuyama-dental.com/tdc/contact.html>

1.4 Emergency telephone number

Emergency Phone No. +1-760-942-7211
 Contact Tokuyama Dental America, Inc.
 Days and hours of operation : 9:00-17:00(PST/PDT), Weekdays, except national holidays in US.
 Language: English only.

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

ACCORDING TO HAZARDOUS PRODUCTS REGULATIONS (HPR) Skin Sens. 1 :May cause an allergic skin reaction.

2.2 Label elements

Product Name OMNICHROMA FLOW

Hazard Pictogram(s)



GHS07

Signal Word(s)

Warning

OMNICHROMA FLOW

Hazard Statement(s)	H317: May cause an allergic skin reaction.
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>

2.3 Other hazards

None known.

2.4 Additional Information

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.	% W/W	Hazard Statement(s)	Hazard Pictogram(s)
COMPOSITE FILLER	-	30-50	Substance not classified as hazardous	none
SILICA-ZIRCONIA FILLER		20-40	Substance not classified as hazardous	none
2-PROPENOIC ACID, 2-METHYL-, 7,7,9(or 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL ESTER	72869-86-4	10-30	Skin Sens. 1 H317	GHS07
NONAMETHYLENDIOL DIMETHACRYLATE	65833-30-9	5-15	Substance not classified as hazardous	none
SILICON DIOXIDE (amorphous)	112945-52-5	1-10	Substance not classified as hazardous	none
BICYCLO[2.2.1]HEPTANE-2,3-DIONE, 1,7,7-TRIMETHYL- (±)-	10373-78-1	<0.1	Skin Irrit. 2 H315 Eye Irrit. 2A H319 STOT SE 3 H335	GHS07
PHENOL, 4-METHOXY-	150-76-5	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 Eye Irrit. 2A H319	GHS07
PHENOL, 2,6-BIS(1,1-DIMETHYLETHYL)-4-METHYL-	128-37-0	<0.1		None

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 : Remove to fresh air immediately. If

OMNICHROMA FLOW

	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. If skin irritation or rash occurs: Get medical advice/attention. Take off immediately all contaminated clothing and wash it before reuse. 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: FIRE-FIGHTING 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.

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

OMNICHROMA FLOW

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 oxidizing 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:
4-Methoxyphenol	150-76-5		5			
Butylated hydroxytoluene (BHT), Inhalable, (2,6-Di-tert-butyl-p-cresol)	128-37-0				10	
Butylated hydroxytoluene (BHT), Inhalable, (2,6-Di-tert-butyl-p-cresol)	128-37-0				10	Comp,

Region

Source

Canada

Regulation respecting occupational health and safety, Permissible Exposure Values for Airborne Contaminants, Canada 2019





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 protective eyewear (goggles, face shield, or safety glasses).
	Skin protection	Wear protective clothing and gloves: Impervious gloves. 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.
	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.

OMNICHROMA FLOW**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****9.1 Information on basic physical and chemical properties**

Appearance	Solid. paste. Colour : White -Slightly Yellowish
Odour	Odorless
Odour Threshold	Not known.
pH	Not known.
Melting Point/Freezing Point	Not known.
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.
oxidizing 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.

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 oxidizing agents.

10.6 Hazardous decomposition products

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

OMNICHROMA FLOW

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity - Ingestion	Not classified. Calculated acute toxicity estimate (ATE) Calc ATE - 555556 Not classified.
Acute toxicity - Skin Contact	Not classified. Not classified.
Acute toxicity - Inhalation	Not classified. Not classified.
Skin corrosion/irritation	Not classified.
Serious eye damage/irritation	Not classified.
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.

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 Other adverse effects

Not known.

OMNICHROMA FLOW**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

This product has been classified in accordance with HPR and the SDS contains all the information required by HPR.

15.1 Canadian Regulations

Domestic Substances List (DSL)	BICYCLO[2.2.1]HEPTANE-2,3-DIONE, 1,7,7-TRIMETHYL-(10373-78-1), PHENOL, 4-METHOXY-(150-76-5), PHENOL, 2,6-BIS(1,1-DIMETHYLETHYL)-4-METHYL (128-37-0)
Export Control List	Not listed
Priority Substances List (PSL)	Not listed
Toxic Substances List	Not listed
National Pollutant Release Inventory (NPRI) Substance List)	PHENOL, 2,6-BIS(1,1-DIMETHYLETHYL)-4-METHYL (128-37-0)

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: This is the first issue.

Training advice Ensure operatives are trained to minimize exposure. Only trained personnel should

OMNICHROMA FLOW

use this material.

Date of First Issue 01-11-2020
 Date of Revision 01-11-2020
 Revision (CA) 1

LEGEND

Hazard Pictogram(s)



GHS07

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

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.

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
 LTEL : Long term exposure limit
 STEL : Short term exposure limit
 STOT : Specific Target Organ Toxicity

Key literature references and sources for data used to compile the SDS ACCORDING TO HAZARDOUS PRODUCTS REGULATIONS (HPR)

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.