

**OMNICHROMA FLOW BULK**

ACCORDING TO US CFR 1910.1200

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

Product Name OMNICHROMA FLOW BULK

**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  
 Zip 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>  
 Office hours 9:00-17:00(PST/PDT), Weekdays, except national holidays in US.

**1.4 Emergency telephone number**

Emergency Phone No. California Poison Control System  
 1 800 222 1222  
 National Capital Poison Center  
 1 800 222 1222

## Address

California Poison Control System - San Francisco Division  
 San Francisco General Hospital  
 Bldg 5 Rm 2A21, 1001 Potrero Ave, San Francisco  
 E-mail address: [coadmin@calpoison.org](mailto:coadmin@calpoison.org)  
<http://www.calpoison.org>

National Capital Poison Center  
 3201 New Mexico Ave, Ste 310, Washington DC  
 Telephone number: +1 202 362 3867  
 Facsimile number: +1 202 362 8377  
 E-mail address: [pc@poison.org](mailto:pc@poison.org)  
<http://www.poison.org>

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

Regulatory Status This Product is Hazardous under the OSHA Hazard Communication Standard.  
 US CFR 1910.1200

Skin Sens. 1 :May cause an allergic skin reaction.

**2.2 Label elements**

According to US CFR 1910.1200  
 Product Name OMNICHROMA FLOW BULK

## 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.  
 P272: Contaminated work clothing must 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.

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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.

**2.3 Other hazards**

Hazards not otherwise classified (HNOC) Not applicable

**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	15-25	Skin Sens. 1 H317	GHS07
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	109-16-0	1-<10	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2A H319	GHS07
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
p-METHOXYPHENOL	150-76-5	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 Eye Irrit. 2A H319	GHS07
2,6-DI-tert-BUTYL-p-CRESOL	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

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: 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 vapors.

Toxic gases/vapors (Carbon monoxide, Carbon dioxide)

**5.3 Advice for firefighters**

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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/sparks/open flames/hot surfaces. - 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 <sup>3</sup> )	STEL (ppm)	STEL (mg/m <sup>3</sup> )	Note:
4-Methoxyphenol	150-76-5		5			OSHA PEL
4-Methoxyphenol	150-76-5		5			ACGIH TLV
2,6-Di-tert-butyl-p-cresol	128-37-0		10			OSHA PEL
Butylated hydroxytoluene (BHT, 2,6-Di-tert-butyl-p-cresol)	128-37-0		2			ACGIH TLV, IFV, A4
2,6-Di-tert-butyl-p-cresol	128-37-0		10			Comp, OSHA PEL

Remark

Notes

OSHA PEL

Occupational Safety and Health (OSHA) Permissible Exposure Limits (PELs).

ACGIH TLV

The American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Values (TLVs®) 2020

IFV

Measured as Inhalable fraction and vapor


A4

Not Classifiable as a Human Carcinogen




**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). Personal protective equipment for eye and face protection should comply with OSHA 1910.133.
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	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. 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.
	Color : White -Slightly Yellowish
Odor	Odorless
Odor 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.
Vapor pressure	Not known.
Vapor 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/sparks/open flames/hot surfaces. - No smoking. Protect from sunlight.

**10.5 Incompatible materials**

Strong oxidizing agents.

**10.6 Hazardous decomposition products**

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

**OMNICHROMA FLOW BULK****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.
Serious eye damage/irritation	Based on available data, the classification criteria are not met. Not classified.
Skin sensitization data	Based on available data, the classification criteria are not met.
Respiratory sensitization data	Calculation method : May cause an allergic skin reaction.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified. Some ingredients are listed in the National Toxicology Program (NTP) Report on Carcinogens, or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, or by OSHA. <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**

Not known.

**12.4 Mobility in soil**

Not known.

**12.5 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.

**OMNICHROMA FLOW BULK****SECTION 14: TRANSPORT INFORMATION****Not classified as hazardous for transport.**

<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>	Not applicable
<b>14.4 Packing group</b>	Not applicable
<b>14.5 Environmental hazards</b>	Not classified as a Marine Pollutant.
<b>14.6 Special precautions for user</b>	Not known
<b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not known

**SECTION 15: REGULATORY INFORMATION****15.1 US Federal Regulations**

This Product is Hazardous under the OSHA Hazard Communication Standard.

Regulatory Status

SARA 311/312 - Hazard Categories Toxic and hazardous substances (29 CFR 1910; Subpart Z)	Not listed
National emission standards for hazardous air pollutants (40 CFR 61.01)	Not listed
SARA Title III Section 313	Not listed
TSCA (Toxic Substance Control Act)	Listed : 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) (Active), 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE (109-16-0) (Active) BICYCLO[2.2.1]HEPTANE-2,3-DIONE, 1,7,7-TRIMETHYL (10373-78-1) (Active), p-METHOXYPHENOL (150-76-5) (Active), 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0) (Active)
CAA 602 - Ozone Depleting Substances (ODS)	Not listed

**15.2 US State Regulations**

State Right to Know Lists

Proposition 65 (California)	Not listed
Minnesota	Listed : p-METHOXYPHENOL (150-76-5), 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0)
New Jersey	Listed : p-METHOXYPHENOL (150-76-5), 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0)
Pennsylvania	Listed : p-METHOXYPHENOL (150-76-5), 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0)
Rhode Island	Listed : p-METHOXYPHENOL (150-76-5), 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0)

**15.3 Other**

OSPAR List of Chemicals for Priority Action	Not listed
OSHA (List of Highly Hazardous Chemicals, Toxics and Reactives)	Not listed
NTP (National Toxicology Program )	listed : 2,6-DI-tert-BUTYL-p-CRESOL (Cas.No. : 128-37-0) Male : rat-negative, mice-negative Female : rat-negative, mice-negative
IARC (International Agency for Research on Cancer )	Listed : 2,6-DI-tert-BUTYL-p-CRESOL (128-37-0) IARC Group 3 Not classifiable as to its carcinogenicity to humans.

**SECTION 16: OTHER INFORMATION**

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

Training advice	Ensure operatives are trained to minimize exposure. Only trained personnel should use this material.
Date of First Issue	01-15-2023

**OMNICHROMA FLOW BULK**

Date of Revision 01-15-2023  
Revision\_(US) 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. 2A : Serious eye damage/irritation, Category 2A  
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 must 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

US CFR 1910.1200

Disclaimers

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