

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 againstIdentified 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<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<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

Product Name

According to US CFR 1910.1200

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 ³)	STEL (ppm)	STEL (mg/m ³)	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.
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.

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.**

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 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 INFORMATIONThe 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

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