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

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 http://www.calpoison.org National Capital Poison Center 3201 New Mexico Ave, Ste 310, Washington DC Telephone number: +1 202 362 3867 Facsimile numer: +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

According to US CFR 1910.1200

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.
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.

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	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. 2 H319 STOT SE 3 H335	GHS07
p-METHOXYPHENOL	150-76-5	<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	<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.
I nhalation	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

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℃
Storage life	Stable under normal conditions.
Incompatible materials	None known. 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/m³)	STEL (ppm)	STEL (mg/m³)	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_Table Z-3	Occupational Safety and Health (OSHA) Permissible Exposure Limits (PELs) Table Z-3 Mineral Dusts.
mg/m3 value divided by (% SiO2 + 2)	The PEL in mg/m3 is calculated by dividing by the percentage SiO2 +2.
CAL-OSHA PEL_Table Z-3	California Division of Occupational Safety and Health (CAL-OSHA) Permissible Exposure Limits (PELs) Table Z-3 Mineral Dusts.
total dust	Total dust form
resp.	Respirable
NIOSH REL Z-3	National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs) from the NIOSH Pocket Guide to Chemical

	Hazards table Z-3: Up to 10-hour time weighted average (TWA) during a 40-hour work week
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.
 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.

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)

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. 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. 2,6-DI-tert-BUTYL-p-CRESOL 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 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

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), 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 (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 or new statements:	This is the first issue.
Training advice	Ensure operatives are trained to minimize exposure. Only trained personnel should use this material.
Date of First Issue	11-01-2020
Date of Revision	11-01-2020
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. 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 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	The information which is contained in this document is based on available data.

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