

SAFETY DATA SHEET

TOKUYAMA UNIVERSAL PRIMER A

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name TOKUYAMA UNIVERSAL PRIMER A

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses **【Medical device】** Primer to enhance bonding between ceramics, metal and resin.
For dental professionals only.

Uses Not Recommended Use only for intended applications.

1.3. Details of the supplier of the safety data sheet

Supplier Tokuyama Dental Italy S.r.l.
Via Chizzalunga, 1,
36066 Sandrigo, Vicenza, Italy
TEL: +39-0444-659650
FAX: +39-0444-750345

Contact person <http://www.tokuyama-dental.com/tdc/contact.html>

Manufacturer Tokuyama Dental Corporation
38-9, Taitou 1-chome, Taitou-ku, Tokyo
110-0016, Japan
TEL: +81-3-3835-2261
FAX: +81-3-3835-2265

1.4. Emergency telephone number

Emergency telephone 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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Flam. Liq. 2 - H225

Health hazards Skin Sens. 1 - H317

Environmental hazards Not Classified

2.2. Label elements

Pictogram



Signal word Danger

Hazard statements H225 Highly flammable liquid and vapour.
H317 May cause an allergic skin reaction.

TOKUYAMA UNIVERSAL PRIMER A

Precautionary statements	<p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.</p> <p>P403+P235 Store in a well-ventilated place. Keep cool.</p> <p>P501 Dispose of contents/ container in accordance with local regulations.</p>
Contains	(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE, 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE
Supplementary precautionary statements	<p>P233 Keep container tightly closed.</p> <p>P240 Ground/ bond container and receiving equipment.</p> <p>P241 Use explosion-proof electrical equipment.</p> <p>P242 Use only non-sparking tools.</p> <p>P243 Take precautionary measures against static discharge.</p> <p>P261 Avoid breathing vapour/ spray.</p> <p>P272 Contaminated work clothing should not be allowed out of the workplace.</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>P370+P378 In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish.</p>
2.3. Other hazards	<p>This product does not contain any substances classified as PBT or vPvB.</p> <p>Endocrine disrupting properties: Not known.</p>

SECTION 3: Composition/information on ingredients
--

3.2. Mixtures

ETHANOL	60-100%
CAS number: 64-17-5	EC number: 200-578-6
Classification	
Flam. Liq. 2 - H225	
(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE	5-10%
CAS number: 1565-94-2	EC number: 216-367-7
Classification	
Skin Sens. 1 - H317	
Aquatic Chronic 3 - H412	
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	1-5%
CAS number: 109-16-0	EC number: 203-652-6
Classification	
Skin Irrit. 2 - H315	
Eye Irrit. 2 - H319	
Skin Sens. 1 - H317	

TOKUYAMA UNIVERSAL PRIMER A

3-TRIMETHOXYSILYLPROPYL METHACRYLATE 1-5% CAS number: 2530-85-0 EC number: 219-785-8
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 3 - H335
6-METHACRYLOXYHEXYL-2-THIOURACIL-5-CARBOXYLATE <1% CAS number: 198623-08-4
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 3 - H335
2,6-DI-tert-BUTYL-p-CRESOL <1% CAS number: 128-37-0 EC number: 204-881-4 M factor (Chronic) = 1
Classification Aquatic Chronic 1 - H410

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
Inhalation	Move affected person to fresh air at once.
Ingestion	Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if any discomfort continues.
Skin contact	Wash skin thoroughly with soap and water.
Eye contact	Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact	Allergic rash.
---------------------	----------------

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	No specific recommendations.
-----------------------------	------------------------------

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with the following media: Foam. Carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

TOKUYAMA UNIVERSAL PRIMER A

Specific hazards	The product is highly flammable. Thermal decomposition or combustion products may include the following substances: Toxic gases or vapours.
Hazardous combustion products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.
5.3. Advice for firefighters	
Protective actions during firefighting	Avoid breathing fire gases or vapours.
Special protective equipment for firefighters	Wear chemical protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions Avoid discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation. Absorb in vermiculite, dry sand or earth and place into containers. Ground/bond container and receiving equipment.

6.4. Reference to other sections

Reference to other sections For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Wear protective clothing as described in Section 8 of this safety data sheet. Keep away from heat, sparks and open flame. Avoid spilling. Ground/bond container and receiving equipment. Static electricity and formation of sparks must be prevented. Use only non-sparking tools. Use explosion-proof electrical, ventilating and lighting equipment. Take precautionary measures against static discharge. All handling should only take place in well-ventilated areas. Avoid contact with skin and eyes. Good personal hygiene procedures should be implemented. Wash hands and any other contaminated areas of the body with soap and water before leaving the work site.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Keep away from heat, sparks and open flame. Protect from sunlight. Store in a refrigerator. Store at temperatures between 0°C/10°F and 32°C/50°F.

Storage class Flammable liquid storage.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

ETHANOL

Long-term exposure limit (8-hour TWA): WEL 1000 ppm 1920 mg/m³

TOKUYAMA UNIVERSAL PRIMER A

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

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³

WEL = Workplace Exposure Limit

8.2. Exposure controls

Appropriate engineering controls	Provide adequate general and local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.
Eye/face protection	The following protection should be worn: Chemical splash goggles.
Hand protection	Wear protective gloves.
Other skin and body protection	Wear appropriate clothing to prevent any possibility of skin contact.
Hygiene measures	Do not smoke in work area. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. When using do not eat, drink or smoke.
Respiratory protection	No specific recommendations. Respiratory protection must be used if the airborne contamination exceeds the recommended occupational exposure limit.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Clear liquid
Colour	Colourless
Odour	Not available.
Odour threshold	Not available.
pH	Technical impossibility to obtain the data.
Melting point	Not available.
Initial boiling point and range	Not available.
Flash point	14°C
Evaporation rate	Not available.
Evaporation factor	Not applicable.
Upper/lower flammability or explosive limits	Not applicable.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	0.819 g/ml
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.

TOKUYAMA UNIVERSAL PRIMER A

Viscosity Not available.

Explosive properties Not available.

Oxidising properties Not available.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity The following materials may react with the product: Strong oxidising agents. Water. Acids.
See the other subsections of this section for further details.

10.2. Chemical stability

Stability The product is highly flammable.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Heating may generate the following products: Toxic gases or vapours.

10.4. Conditions to avoid

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. Water. Acids.

10.6. Hazardous decomposition products

Hazardous decomposition products Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity - Ingestion

Calculation method : Not classified.

Acute toxicity - Skin Contact

Calculation method : Not classified. No data.

Acute toxicity - Inhalation

Calculation method : Not classified. No data.

Skin corrosion/irritation

Calculation method : Not classified. Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Calculation method : Not classified. Based on available data, the classification criteria are not met.

Skin sensitization

Calculation method : May cause an allergic skin reaction.

Respiratory sensitization

Calculation method : Not classified.

Germ cell mutagenicity

Calculation method : Not classified.

TOKUYAMA UNIVERSAL PRIMER A

Carcinogenicity

Calculation method : Not classified.

Reproductive toxicity

Calculation method : Not classified.

Lactation

Calculation method : Not classified.

STOT - single exposure

Calculation method : Not classified. Based on available data, the classification criteria are not met.

STOT - repeated exposure

Calculation method : Not classified.

Aspiration hazard

Calculation method : Not classified. Not applicable.

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

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

TOKUYAMA UNIVERSAL PRIMER A

14.1. UN number

UN No. (ADR/RID)	1133
UN No. (IMDG)	1133
UN No. (ICAO)	1133

14.2. UN proper shipping name

Proper shipping name (ADR/RID)	Adhesives, containing a flammable liquid.
Proper shipping name (IMDG)	Adhesives, containing a flammable liquid.
Proper shipping name (ICAO)	Adhesives, containing a flammable liquid.
Proper shipping name (ADN)	Adhesives, containing a flammable liquid.

14.3. Transport hazard class(es)

ADR/RID class	3
ADR/RID label	3
IMDG class	3
ICAO class/division	3

Transport labels



14.4. Packing group

ADR/RID packing group	II
IMDG packing group	II
ICAO packing group	II

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant
No.

14.6. Special precautions for user

EmS	F-E, S-D
Emergency Action Code	•3YE
Hazard Identification Number (ADR/RID)	33
Tunnel restriction code	(D/E)

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Annex II of MARPOL 73/78
and the IBC Code

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TOKUYAMA UNIVERSAL PRIMER A

EU legislation (EC) No 1907/2006 (REACH).
(EC) No 1272/2008 (CLP).
(EU) No 2015/830.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008 Flam. Liq. 2 - H225: On basis of test data. Skin Sens. 1 - H317: Calculation method.

Training advice Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

Revision comments

Revision date 15/12/2022

Revision 6

Hazard statements in full H225 Highly flammable liquid and vapour.
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.
H412 Harmful to aquatic life with long lasting effects.

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.