

TOKUYAMA UNIVERSAL BOND BOND A

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name TOKUYAMA UNIVERSAL BOND BOND A

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

Identified Use(s) **[Medical Device]** Dental adhesive. For dental professionals only.

Uses Not Recommended Use only for intended applications.

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

Supplier

Company Identification Tokuyama Dental Italy S.r.l.
Address of Supplier Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy
Telephone: +39-0444-659650
Fax +39-0444-750345
E-mail <http://www.tokuyama-dental.com/tdc/contact.html>

1.4 Emergency telephone number

Emergency Phone No. (UK)844 892 0111

Contact 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

National response center

Contact NHS Direct

Emergency Phone No. +44 111

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP) Flam. Liq. 2 :Highly flammable liquid and vapour.
Skin Irrit. 2 :Causes skin irritation.
Skin Sens. 1 :May cause an allergic skin reaction.
Eye Irrit. 2 :Causes serious eye irritation.
STOT SE 3 :May cause drowsiness or dizziness.

2.2 Label elements

According to Regulation (EC) No. 1272/2008 (CLP)
Product Name TOKUYAMA UNIVERSAL BOND BOND A

Hazard Pictogram(s)



GHS02



GHS07

Signal Word(s) Danger

Hazard Statement(s) H225: Highly flammable liquid and vapour.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H336: May cause drowsiness or dizziness.

Precautionary Statement(s) P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.

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P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents/ container in accordance with local regulations.

2.3 Other hazards

None known. This product does not contain any substances classified as PBT or vPvB. Endocrine disrupting properties: Not known.

2.4 Additional Information

Contains: Acetone; (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate; 2-hydroxyethyl methacrylate; 2,2'-ethylenedioxydiethyl dimethacrylate.

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.	EC No. / REACH Registration No.	% W/W	Hazard Statement(s)	Hazard Pictogram(s)
ACETONE	67-64-1	200-662-2	35-55	Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336	GHS02 GHS07
(1-METHYLETHYLIDENE) BIS[4,1-PHENYLENEOXY (2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE	1565-94-2	216-367-7	5-20	Skin Sens. 1 H317 Aquatic Chronic 3 H412	GHS07
2-HYDROXYETHYL METHACRYLATE	868-77-9	212-782-2	5-20	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07
2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	109-16-0	203-652-6	5-10	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07
2-PROPENOIC ACID, 2-METHYL-, 2-HYDROXYETHYL ESTER, PHOSPHATE	52628-03-2	258-053-2	1-5	Skin Irrit. 2 H315 Eye Irrit. 2 H319	GHS07
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0	204-881-4	<0.1	Aquatic Chronic 1 H410	GHS09

Contains no non-classified vPvB substances.

Contains no non-classified substances with a Union workplace exposure limit.

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 : Rescuers should put on approved respiratory protection before entering the area to render first aid. If signs/symptoms continue, get medical attention.

Inhalation

Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

Skin Contact

Take off immediately all contaminated clothing and wash it before reuse. Rinse skin with water. If skin irritation occurs: Get medical advice/attention. Special treatment: Observe directions on label and instructions for use.

Eye Contact

If substance has got into the eyes, immediately wash out with plenty of water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Allergic contact dermatitis. Skin irritation. Eye irritation. Salivation. Cough. Drowsiness. Dizziness. Headache. Sore throat. Nausea. Vomiting. Unconsciousness.

4.3 Indication of any immediate medical attention and special treatment needed

Special treatment: Observe directions on label and instructions for use. Call a POISON CENTER/ doctor if you feel unwell. Treat symptomatically.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media Carbon dioxide, Dry powder, Water spray, Alcohol resistant foam
 Unsuitable extinguishing media Water jet spray

5.2 Special hazards arising from the substance or mixture

Highly flammable liquid and vapour. May decompose in a fire, giving off toxic and irritant vapours. Heating of containers may cause pressure rise, with risk of bursting.

5.3 Advice for firefighters

Keep upwind. Fire fighters should wear complete protective clothing including self-contained breathing apparatus. If it is safe to do so, containers should be removed from fire area because they are likely to rupture under fire conditions. Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing as per section 8. No action should be taken involving personal risk. Evacuate area. Provide adequate ventilation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. IF ON CLOTHING: Remove contaminated clothing immediately. Avoid inhalation of vapours. In case of inadequate ventilation wear respiratory protection. Avoid contact with skin and eyes.

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

Wear protective clothing as per section 8. No open flames, no sparks and no smoking. If safe to do so: Eliminate sources of ignition. Use non-sparking tools. Absorb spillage in suitable inert material. Place in sealable container. Keep container tightly closed. Wash thoroughly after dealing with spillage. Disposal considerations: See Section:13.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Use explosion-proof electrical/ ventilating/ lighting/ equipment. Use non-sparking tools. Take action to prevent static discharges. Wear protective gloves/protective clothing/eye protection/face protection. Wash hands and exposed skin thoroughly after handling. Avoid breathing dust/ fume/ gas/ mist/ vapours/spray. Use only outdoors or in a well-ventilated area. Do not subject to grinding/shock/friction. Avoid contact with skin, eyes or clothing. Contaminated work clothing should not be allowed out of the workplace. Keep containers properly sealed when not in use. Do not handle broken packages without protective equipment. Keep away from food, drink and animal feedingstuffs.

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

Storage temperature (°C): 0-10°C .

Storage life

Stable under normal conditions.

Incompatible materials

Incompatible with organic peroxides. Oxidizing agents, Acids, Alkalis .

7.3 Specific end use(s)

【Medical Device】 Dental adhesive. 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	LTEL	STEL	STEL	Note

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		(8 hr TWA ppm)	(8 hr TWA mg/m ³)	(ppm)	(mg/m ³)	
ACETONE	67-64-1	500	1210	1500	3620	
ACETONE	67-64-1	500	1210			IOELV
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0		10			
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0		10			Comp,





Region	Source
EU	EU Occupational Exposure Limits
United Kingdom	UK Workplace Exposure Limits EH40/2005 (Fourth edition, published 2020)
Remark	Notes
IOELV	Indicative Occupational Exposure Limit Values.

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Provide adequate ventilation. Use explosion-proof electrical/ ventilating/ lighting/ equipment. Observe any occupational exposure limits for the product or ingredients.

8.2.2. Personal protection equipment

	Eye Protection	Wear eye protection with side protection (EN166).
	Skin protection	Wear protective clothing and gloves: Impervious gloves (EN 374). 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. Wear a suitable respirator if the ventilation is not sufficient to keep the solvent vapour concentration below the occupational limit values.
	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	Liquid. Colourless ~ Yellow
Odour	Characteristic
Odour threshold	Not known.
pH	Not known.
Melting point/freezing point	Not known.
Initial boiling point and boiling range	>35°C
Flash Point	-17.6 °C
Evaporation rate	Not known.
Flammability (solid, gas)	Highly flammable liquid and vapour.
Upper/lower flammability or explosive limits	Not known.
Vapour pressure	Not known.
Vapour density	Not known.
Density (g/ml)	Not known.
Relative density	0.97
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.

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Oxidising properties Not known.

9.2 Other information

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

May react violently with: Oxidising materials. Organic peroxides/hydroperoxides.

10.2 Chemical Stability

Stable at normal ambient temperatures and when used as recommended. Stable under the prescribed storage conditions.

10.3 Possibility of hazardous reactions

The following materials may react strongly with the product: Oxidising materials. Organicperoxides/ hydroperoxides.

10.4 Conditions to avoid

Avoid friction, sparks, or other means of ignition. Keep away from heat, sources of ignition and direct sunlight. Avoid contact with moisture.

10.5 Incompatible materials

Strong oxidising agents, Acids, Alkalis.

10.6 Hazardous decomposition products

Combustion or thermal decomposition may evolve toxic vapours. Toxic gases/vapours(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

Acute toxicity - Skin Contact

Not classified.

Acute toxicity - Inhalation

Not classified.

Skin corrosion/irritation

Calculation method : Causes skin irritation.

Serious eye damage/irritation

Calculation method : Causes serious eye irritation.

Skin sensitization data

Calculation method : May cause an allergic skin reaction.

Respiratory sensitization data

Not classified.

Germ cell mutagenicity

Not classified.

Carcinogenicity

Not classified.

2,6-DI-tert-BUTYL-p-CRESOL (Cas.No. : 128-37-0)

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

Calculation method : May cause drowsiness or dizziness.

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.

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.

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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

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

14.1 UN number

UN No. 1133

14.2 UN proper shipping name

UN proper shipping name ADHESIVES

14.3 Transport hazard class(es)

ADR/RID

ADR/RID Class 3

ADR Classification Code F1

Special Provisions 640D

Limited Quantities 5 L

Excepted Quantities E2

Emergency Action Code •3YE

Mixed Packing Instructions for Packages P001 IBC02 R001

Special Packing Provisions for Packages PP1

Mixed Packing Instructions for Packages MP19

Packing Instructions for Portable Tanks T4

Special Provisions for Portable Tanks TP1 TP8

Tank Code for Tanks LGBF

Special Provisions for Tanks

Vehicle for Tank Carriage FL

ADR Transport Category 2

Tunnel Restriction Code D/E

Special Provisions for Carriage - Packages

Special Provisions for Carriage - Bulk

Special Provisions for Carriage - Loading, Unloading and Handling

Special Provisions for Carriage - Operation S2 S20

ADR HIN 33

IMDG

IMDG Class 3

Special Provisions 640D

Limited Quantities 5 L

Excepted Quantities E2

Mixed Packing Instructions for Packages P001 IBC02 R001

Special Packing Provisions for Packages PP1

Packing Instructions for Portable Tanks T4

Special Provisions for Portable Tanks TP1 TP8

IMDG EMS F-E, S-D

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Stowage and Handling Category B
Segregation
Marine Pollutant

ICAO/IATA

IATA Proper Shipping Name ADHESIVES
Excepted Quantities E2
Passenger and Cargo Aircraft Limited Y341
Quantities Packing Instructions
Passenger and Cargo Aircraft Limited 1L
Quantities Max net Qty
Passenger and Cargo Aircraft Packing 353
Instructions
Passenger and Cargo Aircraft Max net 5L
Qty
Cargo Aircraft Packing Instructions 364
Cargo Aircraft Max net Qty 60L
Special Provisions A3
Emergency Response Guidebook (ERG) 3L
Code

Labels

Labels

3

**14.4 Packing group**

Packing group

II

14.5 Environmental hazards

Environmental hazards

Not classified as a Marine Pollutant.

14.6 Special precautions for user

Special precautions for user

Not known.

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

No information available

SECTION 15: REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation	Not listed
REACH: ANNEX XIV list of substances subject to authorisation	Not listed
REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not listed
Community Rolling Action Plan (CoRAP)	2-hydroxyethyl methacrylate (868-77-9), 2,6-di-tert-butyl-p-cresol (128-37-0)
Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants	Not listed
Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer	Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed
Directive 93/42/EEC	This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the

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	product is classified and labelled according to the CLP regulation.
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National regulations

Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements:

Training advice	Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.
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Date of First Issue	20-11-2016
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Date of Revision	15-12-2022
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Revision (UK)	4
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LEGEND

Hazard Pictogram(s)



GHS02



GHS07

Hazard classification

GHS09: GHS: Environment

Flam. Liq. 2 : Flammable liquid, Category 2

Acute Tox. 4 : Acute toxicity, Category 4

Skin Irrit. 2 : Skin corrosion/irritation, Category 2

Skin Sens. 1 : Skin sensitization, Category 1

Skin Sens. 1B : Skin sensitization, Category 1B

Eye Irrit. 2 : Serious eye damage/irritation, Category 2

STOT SE 3 : Specific target organ toxicity — single exposure, Category 3

Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1

Aquatic Chronic 3 : Hazardous to the aquatic environment, Chronic, Category 3

Hazard Statement(s)

H225: Highly flammable liquid and vapour.

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

H410: Very toxic to aquatic life with long lasting effects.

H412: Harmful to aquatic life with long lasting effects.

Precautionary Statement(s)

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233: Keep container tightly closed.

P240: Ground and bond container and receiving equipment.

P241: Use explosion-proof electrical/ventilating/lighting/equipment.

P242: Use non-sparking tools.

P243: Take action to prevent static discharges.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash hands and exposed skin thoroughly after handling.

P271: Use only outdoors or in a well-ventilated area.

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.

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312: Call a POISON CENTER/doctor if you feel unwell.

P321: Specific treatment (see Medical Advice on this label).

P332+P313: If skin irritation occurs: Get medical advice/attention.

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Acronyms

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P337+P313: If eye irritation persists: Get medical advice/attention.
P362+P364: Take off contaminated clothing and wash it before reuse.
P370+P378: In case of fire: Use water spray, dry powder or carbon dioxide to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents/ container in accordance with local regulations.
ADN : European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS : Chemical Abstracts Service
CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL : Derived No Effect Level
EC : European Community
EINECS : European Inventory of Existing Commercial Chemical Substances
IATA : International Air Transport Association
IBC : Intermediate Bulk Container
ICAO : International Civil Aviation Organization
IMDG : International Maritime Dangerous Goods
LTEL : Long term exposure limit
PBT : Persistent, Bioaccumulative and Toxic
PNEC : Predicted No Effect Concentration
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals
RID : Regulations concerning the International Carriage of Dangerous Goods by Rail
STEL : Short term exposure limit
STOT : Specific Target Organ Toxicity
UN : United Nations

Disclaimers

vPvB : very Persistent and very Bioaccumulative
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.