TOKUYAMA UNIVERSAL BOND II 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 II 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.

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

Product Name

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

Hazard Pictogram(s)





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.

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P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

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

 $Contains: Acetone; \ (1-methylethylidene) bis [4,1-phenyleneoxy (2-hydroxy-3,1-phenyleneoxy (2-hydroxy-3,1-pheny$

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

J.Z MIXLUIGS					
HAZARDOUS	CAS No.	EC No. /	%	Hazard Statement(s)	Hazard
INGREDIENT(S)		REACH Registration No.	W/W		Pictogram(s)
ACETONE	67-64-1	200-662-2	35-55	Flam. Liq. 2 H225	GHS02
				Eye Irrit. 2 H319	GHS07
				STOT SE 3 H336	
(1-METHYLETHYLIDENE)	1565-94-2	216-367-7	5-20	Skin Sens. 1 H317	GHS07
BIS[4,1-PHENYLENEOXY				Aquatic Chronic 3 H412	
(2-HYDROXY-3,1-PROPANEDIYL)]					
BISMETHACRYLATE					
2-HYDROXYETHYL	868-77-9	212-782-2	5-20	Skin Irrit. 2 H315	GHS07
METHACRYLATE				Skin Sens. 1 H317	
				Eye Irrit. 2 H319	
2,2'-ETHYLENEDIOXYDIETHYL	109-16-0	203-652-6	5-10	Skin Irrit. 2 H315	GHS07
DIMETHACRYLATE				Skin Sens. 1 H317	
				Eye Irrit. 2 H319	
2-PROPENOIC ACID, 2-METHYL-,	52628-03-2	258-053-2	1-5	Skin Irrit. 2 H315	GHS07
2-HYDROXYETHYL ESTER,				Eye Irrit. 2 H319	
PHOSPHATE					
MEQUINOL	150-76-5	205-769-8	<0.1	Acute Tox. 4 H302	GHS07
				Skin Sens. 1 H317	
				Eye Irrit. 2 H319	
2,6-DI-tert-BUTYL-p-CRESOL	128-37-0	204-881-4	<0.1	Aquatic Chronic 1 H410	GHS09

HAZARDOUS	CAS No.	Specific	M-factor,	ATE
INGREDIENT(S)		concentration limits		
MEQUINOL	150-76-5			Acute Tox. 4 (H302): 500

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

General

4.1 Description of first aid measures

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

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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.

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

Storage temperature

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 (°C): 0-25°C

Storage life Stable under normal conditions.

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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
		(8 hr TWA ppm)	(8 hr TWA mg/m³)	(ppm)	(mg/m³)	
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

Liquid. Appearance

Colour: Yellow Characteristic Not known. Not known. Melting point/freezing point Not known. Not known.

Initial boiling point and boiling range Flash Point -15.5 °C Evaporation rate Not known.

Flammability (solid, gas) Highly flammable liquid and vapour.

Not known.

Upper/lower flammability or explosive

limits

Odour

Odour threshold

Vapour pressure Not known.

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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
Auto-ignition temperature
Decomposition Temperature (°C)
Viscosity
Not known.
Explosive properties
Not known.
Oxidising properties
Not known.
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

Serious eye damage/irritation

Skin sensitization data

Calculation method : Causes skin irritation.

Calculation method : Causes serious eye irritation.

Calculation method : May cause an allergic skin reaction.

Respiratory sensitization data
Germ cell mutagenicity
Carcinogenicity
Not classified.
Not classified.
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

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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

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

ADR Classification Code

Special Provisions

640D

Limited Quantities

5 L

Excepted Quantities

E2

Emergency Action Code

33

ADR Classification Code

51

Excepted Quantities

E2

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 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 - S2 S20

Operation

ADR HIN 33

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IMDG

IMDG Class3Special Provisions640DLimited Quantities5 LExcepted QuantitiesE2

Mixed Packing Instructions for Packages P001 IBC02 R001

Special Packing Provisions for Packages PP1
Packing Instructions for Portable Tanks Special Provisions for Portable Tanks TP1 TP8
IMDG EMS F-E, S-D
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



14.4 Packing group

Packing group I

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	Not listed
High Concern for Authorisation	
REACH: ANNEX XIV list of substances	Not listed
subject to authorisation	
REACH: Annex XVII Restrictions on the	Not listed
manufacture, placing on the market and	
use of certain dangerous substances,	
mixtures and articles	
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	Not listed

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European Parliament and of the Council on persistent organic pollutants	
1 0 1	Not listed
substances that deplete the ozone layer	
	Not listed
European Parliament and of the Council	
concerning the export and import of	
hazardous chemicals	
	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 product is classified and labelled according to the CLP regulation.

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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LEGEND

Hazard Pictogram(s)





GHS09: GHS: Environment

Hazard classification 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.

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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.

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

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.

Acronyms

Disclaimers

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