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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 03.08.2022 Version number 4 (replaces version 3) Revision: 03.08.2022

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

- · 1.1 Product identifier
 - · Trade name: iBond Universal
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
 - · Application of the substance / the mixture Dental bonding material
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· Informing department: E-Mail: msds@kulzer-dental.com

· 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
 - Classification according to Regulation (EC) No 1272/2008

H225 Highly flammable liquid and vapour. Flam. Lig. 2

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation. Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H336 May cause drowsiness or dizziness.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
 - Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms





GHS02 GHS07

- · Signal word Danger
- · Hazard-determining components of labelling:

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

acetone

4-methacryloxyethyltrimellitic acid anhydride

Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction. H336 May cause drowsiness or dizziness.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition P210

sources. No smoking.

P261 Avoid breathing mist/vapours/spray. Avoid release to the environment. P273

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P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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

· Additional information:

Contains isocyanates. May produce an allergic reaction.

· 2.3 Other hazards -

· Results of PBT and vPvB assessment

· **PBT:** Not applicable. · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - · Description: -

· Dangerous components:		
EINECS: 200-662-2 Reg.nr.: 01-2119471330-49-xxxx	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	25-50%
EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	≥10-<25%
	4-methacryloxyethyltrimellitic acid anhydride Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
 - · After inhalation

Supply fresh air and call for doctor for safety reasons.

In case of unconsciousness bring patient into stable side position for transport.

- · After skin contact If skin irritation continues, consult a doctor.
- · After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

- 4.2 Most important symptoms and effects, both acute and delayed
- No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

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SECTION 5: Firefighting measures

- 5.1 Extinguishing media
 - · Suitable extinguishing agents
 - CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
 - · For safety reasons unsuitable extinguishing agents Water with a full water jet.
- · 5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
 - · Protective equipment: No special measures required.
 - Additional information -

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Prevent material from reaching sewage system, holes and cellars.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Ensure adequate ventilation.

Send for recovery or disposal in suitable containers.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

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SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Keep containers tightly sealed.
 - Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
 - Storage
 - · Requirements to be met by storerooms and containers: Store in cool location.
 - · Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions:

Keep receptacle tightly sealed.

Protect from the effects of light.

Store in cool, dry conditions in well sealed containers.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Components with critical values that require monitoring at the workplace:

67-64-1 acetone

WEL (Great Britain) Short-term value: 3620 mg/m³, 1500 ppm Long-term value: 1210 mg/m³, 500 ppm

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,	IOELV (European Union) Long-term value: 1210 mg/m³, 500 ppm			
	DNELs			
	67-64-1 acetone			
Oral	general population, long		, , , , , , , , , , , , , , , , , , ,	
Dermal	worker industrial, long ter		186 mg/Kg/d (not defined)	
	general population, long	-	62 mg/Kg/d (not defined)	
Inhalative	worker industrial, long ter	-	1,210 mg/m3 (not defined)	
	worker industrial, long ter		2,420 mg/m3 (not defined)	
		•	200 mg/m3 (not defined)	
72869-86-	72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-di bismethacrylate			
Oral	general population, long	term, systemic	0.3 mg/Kg (not defined)	
Dermal	worker industrial, long tel	rm, systemic	1.3 mg/Kg/d (not defined)	
	general population, long term, systemic		0.7 mg/Kg/d (not defined)	
Inhalative	worker industrial, long tel	rm, systemic	3.3 mg/m3 (not defined)	
	general population, long	term, systemic	0.6 mg/m3 (not defined)	
· PNE	PNECs			
67-64-1 ac	etone			
freshwater	•	10.6 mg/l (not	defined)	
marine wa	ter	1.06 mg/l (rabl	pit)	
sewage tre	eatment plant	19.5 mg/l (not	defined)	
sediment,	dry weight, freshwater	30.4 mg/Kg (ne	ot defined)	
sediment,	dry weight, marine water	3.04 mg/Kg (no	ot defined)	
soil, dry we	soil, dry weight 0.112 mg/Kg (not defined)	
72869-86-	72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy bismethacrylate			
freshwater	freshwater 0.01 n		defined)	
marine wa	marine water 0.001 mg/l (no		t defined)	
sewage tre	sewage treatment plant 3.61 mg/l (not		defined)	
sediment,	sediment, dry weight, freshwater 4.56 mg/s		ot defined)	
sediment,	sediment, dry weight, marine water		ot defined)	
soil, dry we	soil, dry weight 0.91 mg/Kg (no		ot defined)	

Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- · Appropriate engineering controls No further data; see item 7.
- Individual protection measures, such as personal protective equipment
 General protective and hygienic measures
 Avoid contact with the eyes.

Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

· Breathing equipment: Use breathing protection against the effects of fumes/dust/aerosol.

Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.

recommended

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR Nitrile rubber, NBR

- · Eye/face protection Tightly sealed safety glasses.
- Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

· Physical state Fluid Clear

Smell: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Not determined

Boiling point or initial boiling point and

boiling range 55 °C

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: -19 °C

• Flash point: -19 °C
• Decomposition temperature: Not determined.

SADT

· **pH** Not determined.

· Viscosity:

· Kinematic viscosity
· dynamic:

Not determined.

Not determined.

Solubility

• **Water:** Partly miscible

· Partition coefficient n-octanol/water (log

value)
Not determined.
Steam pressure:
Not determined.

Density and/or relative density

Density at 20 °C
 Relative density
 Vapour density
 Not determined.
 Not determined.

• 9.2 Other information No further relevant information available.

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· Appearance:

Form: Liquid

· Important information on protection of health and environment, and on safety.

· Self-inflammability: Product is not selfigniting.

Product is not explosive. However, formation of Explosive properties: explosive air/vapour mixtures is possible.

Change in condition

Evaporation rate Not determined.

· Information with regard to physical hazard classes

Void · Explosives · Flammable gases Void · Aerosols Void Oxidising gases Gases under pressure Void Void

· Flammable liquids Highly flammable liquid and vapour.

· Flammable solids Void · Self-reactive substances and mixtures Void Void · Pyrophoric liquids Pyrophoric solids Void Self-heating substances and mixtures Void

Substances and mixtures, which emit

flammable gases in contact with water Void · Oxidising liquids Void · Oxidising solids Void Organic peroxides
Corrosive to metals Void Void · Desensitised explosives Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- Conditions to be avoided: Protect from heat and direct sunlight.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None
 - Additional information: -

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
 - Acute toxicity Based on available data, the classification criteria are not met.
 - LD/LC50 values that are relevant for classification:

Oral	LD50	5,800 mg/kg (rat)
Dermal	LD50	>15,800 mg/kg (rabbit)

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Inhalative	LC50/4 h	76 mg/l (rat)
72869-86-	4 7,7,9(oı bismetl	7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl nacrylate
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
70293-55-	9 4-metha	acryloxyethyltrimellitic acid anhydride
Oral	LD50	>2,000 mg/kg (mouse)
Dermal	LD50	>2,000 mg/kg (mouse)

· Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

- Germ cell mutagenicity Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure

May cause drowsiness or dizziness.

- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
 - Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity · Aquatic toxicity:

67-64-1 acetone

EC50/48h	8,800 mg/l (daphnia)	
LC50/96h	6,210 mg/l (fish) (OECD 203)	
72869-86-4 7 b	72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)	
LC50/96h	10.1 mg/l (fish) (OECD 203)	
ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)	
NOEC / 72h	0.21 mg/l (algae) (OECD 201)	

12.2 Persistence and degradability

67-64-1 acetone

Biodegradation 90.9 % /28d (not defined) (OECD 301D)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Biodegradation 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

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- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
 - Additional ecological information:

General notes:
Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

Recommendation

Disposal must be made according to official regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
 - Recommendation: Disposal must be made according to official regulations.

14.1 UN number or ID number · ADR, IMDG, IATA	UN1090	
14.2 UN proper shipping name · ADR · IMDG, IATA	1090 ACETONE solution ACETONE solution	
14.3 Transport hazard class(es)		
· ADR		
· Class · Label	3 (F1) Flammable liquids. 3	
· IMDG, IATA		
· Class · Label	3 Flammable liquids. 3	
14.4 Packing group · ADR, IMDG, IATA	II	
14.5 Environmental hazards: • Marine pollutant:	No	
14.6 Special precautions for user	Warning: Flammable liquids.	



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· Kemler Number: · EMS Number: · Stowage Category	33 F-E,S-D E
· 14.7 Maritime transport in bulk according to IMO instruments	o Not applicable.
· Transport/Additional information:	-
ADR Limited quantities (LQ) Excepted quantities (EQ) Transport category Tunnel restriction code	1L Code: E2 Maximum net quantity per inner packaging 30 ml Maximum net quantity per outer packaging 500 ml 2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging 30 ml Maximum net quantity per outer packaging 500 ml
· UN "Model Regulation":	UN 1090 ACETONE SOLUTION, 3, II

SECTION 15: Regulatory information

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

No further relevant information available.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

Highly flammable liquid and vapour. H225

H315 Causes skin irritation.

May cause an allergic skin reaction. H317

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H411 Toxic to aquatic life with long lasting effects.

EUH066 Repeated exposure may cause skin dryness or cracking.

EUH204 Contains isocyanates. May produce an allergic reaction.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Air Transport Association

IMAC: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids — Category 2 Skin Irrit. 2: Skin corrosion/irritation — Category 2 Eye Irrit. 2: Serious eye damage/eye irritation — Category 2 Skin Sens. 1: Skin sensitisation — Category 1 Skin Sens. 1B: Skin sensitisation — Category 1B STOT SE 3: Specific target organ toxicity (single exposure) — Category 3 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard — Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard — Category 3 * Data compared to the previous version altered.