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Safety data sheet according to UK REACH

Version number 4 (replaces version 3) Printing date 17.03.2025 Revision: 17.03.2025

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. Liq. 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.

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· Precautionary statements

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

sources. No smoking.

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

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

hearing 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:

Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.

· 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:		
CAS: 67-64-1 EINECS: 200-662-2 Index number: 606-001-00-8 Reg.nr.: 01-2119471330-49-xxxx	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	25-50%
CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-134-00-4 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%
CAS: 70293-55-9	4-methacryloxyethyltrimellitic acid anhydride Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	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.

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· 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.

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.

-

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.

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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.

8.1 Contro	ol parameters		
· Compo	onents with critical valu	es that require	e monitoring at the workplace:
67-64-1 ad			
WEL (Gre	at Britain) Short-teri	m value: 3620 r	mg/m³, 1500 ppm
10511/6			ng/m³, 500 ppm
	uropean Union) Long-terr	n value: 1210 n	ng/m², 500 ppm
· DNI	<u>_</u>		
67-64-1 ac		1	00 (1/2) (1.24
Oral	general population, long	-	,
Dermal	worker industrial, long te		186 mg/Kg/d (not defined)
lll		-	62 mg/Kg/d (not defined)
innaiative	worker industrial, long te		1,210 mg/m3 (not defined)
	worker industrial, long te		2,420 mg/m3 (not defined)
72060 06			200 mg/m3 (not defined) xo-3,14-dioxa-5,12-diazahexadecane-1,16-d
72009-00-	bismethacrylate	uny1-4, 13-410.	x0-3, 14-010xa-3, 12-01a2a11exa0eCa11e-1, 10-0
Oral	general population, long term, systemic		0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic		1.3 mg/Kg/d (not defined)
	general population, long term, systemic		0.7 mg/Kg/d (not defined)
Inhalative	Inhalative worker industrial, long ter		3.3 mg/m3 (not defined)
general population, long term		term, systemic	0.6 mg/m3 (not defined)
· PNI	ECs		
67-64-1 ad	cetone		
freshwater		10.6 mg/l (not defined)	
marine water		1.06 mg/l (rabbit)	
sewage treatment plant		19.5 mg/l (not defined)	
sediment, dry weight, freshwater		30.4 mg/Kg (not defined)	
sediment, dry weight, marine water		3.04 mg/Kg (not defined)	
		0.112 mg/Kg (
72869-86-	4 7,7,9(or 7,9,9)-trime bismethacrylate	thyl-4,13-dio	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d
		0.01 mg/l (not defined)	
marine water		0.001 mg/l (not defined)	
-	eatment plant	3.61 mg/l (not defined)	
sediment,	dry weight, freshwater	4.56 mg/Kg (n	ot defined)



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sediment, dry weight, marine water 0.46 mg/Kg (not defined) soil, dry weight 0.91 mg/Kg (not 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 section 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

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
 - · Colour:
 - · Smell:
 - Odour threshold:

· Melting point/freezing point:

Liquid Clear

Characteristic

Not determined.

Not determined

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· Boiling point or initial boiling point and

55 °C

boiling range Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined. Upper: Not determined.

Flash point: 1.5 °C

Decomposition temperature: Not determined.

· pH · Viscosity: Not determined.

· Kinematic viscosity Not determined. · dynamic: 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 0.99 g/cm3 Not determined. Relative density · Vapour density Not determined.

9.2 Other information

No further relevant information available.

· Appearance:

Fluid Form:

· 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.

Solvent content:

Water: 19.0 % · Solids content: 19.1 %

· Change in condition

Not determined. · Evaporation rate

Information with regard to physical hazard

classes

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

· Flammable liquids Highly flammable liquid and vapour.

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

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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	Void	
· Corrosive to metals	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.

· I D/I C50 values	that are	relevant for	classification:

67-64-1 ad	cetone		
Oral	LD50	5,800 mg/kg (rat)	
Dermal	LD50	>15,800 mg/kg (rabbit)	
Inhalative	LC50/4 h	76 mg/l (rat)	
72869-86-	72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	

- · Primary irritant effect:
 - 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.

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· Aspiration hazard Based on available data, the classification criteria are not met.

11.2 Information on other hazards

· Endocrine disrupting properties

128-37-0 2,6-di-tert-butyl-p-cresol

List II

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

67-64-1 acet	one	
EC50/48h	8,800 mg/l (daphnia)	
LC50/96h	250/96h 6,210 mg/l (fish) (OECD 203)	
72869-86-4 7	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl	
	nismethacrylate // / / / / / / / / / / / / / / / / /	
b		
EC50/48h	oismethacrylate	

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.
 - · 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.

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

SECTION 14: Transport information	ı en		
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.		
Kemler Number: EMS Number:	33 F-E,S-D		
· Stowage Category	E		
· 14.7 Maritime transport in bulk according instruments	to IMO Not applicable.		
· Transport/Additional information:	-		
ADR Limited quantities (LQ) Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inne packaging: 30 ml Maximum net quantity per outer		



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packaging: 500 ml

· Transport category 2 · Tunnel restriction code D/E

·IMDG

Limited quantities (LQ)

Excepted quantities (EQ) 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.

· Poisons Act

Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

67-64-1 acetone

Listed

· Reportable poisons

None of the ingredients is listed.

· 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

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.

H335 May cause respiratory 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.

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· 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 Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances 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

vPvB: very Persistent and very Bioaccumulative

vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 4: Acute toxicity – Category 4
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 approximation of the previous version altered

* Data compared to the previous version altered.