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

Printing date 01.08.2018 Version number 3 Revision: 01.08.2018

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

- · 1.1 Product identifier
 - · Trade name: iBOND Total Etch
- · 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)

· 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

Flam. Liq. 3 H226 Flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

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

Hazard pictograms









GHS02 GHS05 GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labelling:

2-hydroxyethyl methacrylate

glutaral

4-methacryloxyethyltrimellitic acid anhydride

· Hazard statements

H226 Flammable liquid and vapour.

H315 Causes skin İrritation.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

· Precautionary statements

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

sources. No smoking.

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

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

Immediately call a POISON CENTER/doctor. P310

P405 Store locked up.

· 2.3 Other hazards -

- · Results of PBT and vPvB assessment
 - PBT: Not applicable. · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
 - Description: -

Bescription.		
· Dangerous components:		
	ethanol Flam. Liq. 2, H225	25-50%
EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
	Poly(methacrylic-oligo-acrylic acid) Eye Irrit. 2, H319	0-5%
	4-methacryloxyethyltrimellitic acid anhydride Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	0-5%
EINECS: 203-856-5	glutaral Acute Tox. 3, H301; Acute Tox. 3, H331; Resp. Sens. 1, H334; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Skin Sens. 1, H317	0-5%
	diurethandimethacrylate Aquatic Chronic 3, H412	0-5%

[·] 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: consult doctor in case of symptoms.
 - · After skin contact instantly wash with water and soap and rinse thoroughly.
 - · After eye contact

Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

Instantly call for doctor.

- 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: Put on breathing apparatus.
 - 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:

Do not allow to enter the ground/soil.

No special measures required.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). Send for recovery or disposal in suitable containers.

· 6.4 Reference to other sections

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

-

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Keep containers tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· 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: No special requirements.
 - Information about storage in one common storage facility: Not required.
 - Further information about storage conditions: Store cool (not above 25 ℃).
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 8.1 Control parameters
 - Components with critical values that require monitoring at the workplace:

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

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111-30-8 ຢູ	glutaral		
WEL Sho Long	rt-term va g-term val	lue: 0.2 mg/m³, 0.05 lue: 0.2 mg/m³, 0.05	5 ppm i ppm
· L	DNELs		
64-17-5 et	hanol		
Oral	ge.pop., i	l.te, syst.	87 mg/Kg (nd)
Dermal	worker pi	rofess., l.te., syst.	343 mg/Kg/d (nd)
	ge.pop., a	acu., local	950 mg/Kg/d (nd)
	ge.pop., i	l.te, syst.	206 mg/Kg/d (nd)
Inhalative	worker pi	rofess., acute, local	1900 mg/m3 (nd)
	worker pi	rofess., l.te., syst.	1900 mg/m3 (nd)
	ge.pop., a	acu., local	950 mg/m3 (nd)
	ge.pop., i	l.te, syst.	114 mg/m3 (nd)
.	PNECs		
64-17-5 et	hanol		
freshwater	r	0.96 mg/l (nd)	
marine wa	ter	0.79 mg/l (nd)	
STP		580 mg/l (nd)	
sedim., dи	v, fre.wat.	3.6 mg/Kg (nd)	
soil,dw		0.63 mg/Kg (nd)	

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

· 8.2 Exposure controls

Personal protective equipment

· General protective and hygienic measures
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.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

· Breathing equipment: Breathing protection recommended.

Protection of hands:

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

Solvent resistant gloves

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 protection: Tightly sealed safety glasses.

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· Body protection: Light weight protective clothing

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9.1 Information on basic physical General Information	and chemical properties
· Appearance:	
· Form:	Fluid
Colour:	Yellowish
· Smell:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
Change in condition	
Melting point/freezing point	t: Not determined
Initial boiling point and boil	
· Flash point:	24 ℃
· Inflammability (solid, gaseous,) Not applicable.
· Ignition temperature:	425 ℃
· Decomposition temperature	e: Not determined.
· Self-inflammability:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· Critical values for explosion:	
· Lower:	3,5 Vol %
· Upper:	15,0 Vol %
· Steam pressure at 20 ℃:	57 hPa
Density at 20 ℃	1 g/cm³
· Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol	/water: Not determined.
· Viscosity:	
dynamic:	Not determined.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.

· kinematic:

· 9.2 Other information

10.2 Chemical stability
 Conditions to be avoided: No decomposition if used and stored according to specifications.
 10.3 Possibility of hazardous reactions No dangerous reactions known
 10.4 Conditions to avoid No further relevant information available.

Not determined.

No further relevant information available.

- · 10.5 Incompatible materials: No further relevant information available.

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· 10.6 Hazardous decomposition products: None

· Additional information: -

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
 - · Acute toxicity Based on available data, the classification criteria are not met.

C50 valu	es that are relevant for classification:
anol	
.D50	6200 mg/kg (rat)
.C50/4 h	95.6 mg/l (rat)
diuretha	ndimethacrylate
.D50	>5000 mg/kg (rat)
hydroxye	ethyl methacrylate
.D50	5564 mg/kg (rat)
.D50	>3000 mg/kg (can)
crylic-ol	igo-acrylic acid)
.D50	>5000 mg/kg (rat)
4-metha	cryloxyethyltrimellitic acid anhydride
.D50	> 2000 mg/kg (mouse)
.D50	> 2000 mg/kg (mouse)
diuretha	ndimethacrylate
.D50	>5000 mg/kg (rat)
	anol D50 C50/4 h diuretha D50 hydroxyo D50 Crylic-ol D50 4-metha D50 D50 diuretha

- Primary irritant effect:
 - Skin corrosion/irritation

Causes skin irritation.

- · Serious eve damage/irritation Causes sérious eye damage.
- · Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 · 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 respiratory irritation.

- 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.

SECTION 12: Ecological information

- · 12.1 Toxicity
 - · Aquatic toxicity:

868-77-9 2-hydroxyethyl methacrylate

LC50/96h | 227 mg/l (fish)

72869-86-4 diurethandimethacrylate

LC50/96h 10.1 mg/l (fish)

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- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
 - Additional ecological information:
 - · General notes: Avoid transfer into the environment.
- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - Recommendation

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

European waste catalogue

18 01 06 chemicals consisting of or containing dangerous substances

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

|--|

· 14.1 UN-Number

· ADR, IMDG, IATA UN1170

· 14.2 UN proper shipping name

• ADR 1170 ETHANOL SOLUTION
• IMDG ETHANOL (ETHYL ALCOHOL)
• IATA Ethanol

· 14.3 Transport hazard class(es)

· ADR



• Class 3 (F1) Flammable liquids. 4 sabel 3

· IMDG, IATA



ClassLabel3 Flammable liquids.3

· 14.4 Packing group · ADR, IMDG, IATA

IATA III

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· 14.5 Environmental hazards:

Marine pollutant: No · 14.6 Special precautions for user Warning: Flammable liquids. Kemler Number: 30 · EMS Number: F-E,S-D · Stowage Category · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. · Transport/Additional information: · ADR · Limited quantities (LQ) Excepted quantities (ÉQ) Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer

packaging: 1000 ml · Transport category · Tunnel restriction code D/E

· IMDG

· Limited quantities (LQ) 5L · Excepted quantities (ÉQ) Code: E1

Maximum net quantity per inner

packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

UN "Model Regulation": UN1170, ETHANOL (ETHYL ALCOHOL), 3, III

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or
 - · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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.

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H400 Very toxic to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

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Abbreviations and acronyms:

ADR: Accord européen sur le transport 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

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 (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
PVB: very Persistent and very Bioaccumulative

vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Flam. Liq. 3: Flammable liquids – Category 3

Flam. Ltq. 3: Flammable liquids — Category 3
Acute Tox. 3: Acute toxicity — Category 3
Skin Corr. 1B: Skin corrosion/irritation — Category 1B
Skin Irrit. 2: Skin corrosion/irritation — Category 2
Eye Dam. 1: Serious eye damage/eye irritation — Category 1
Eye Irrit. 2: Serious eye damage/eye irritation — Category 2
Resp. Sens. 1: Respiratory sensitisation — Category 1
Skin Sens. 1: Skin sensitisation — Category 1
STOT SE 2: Sensitis target organ toxicity (single exposure) —

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.