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Revision: 21.12.2023

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

Printing date 21.12.2023

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
 - · Trade name: Charisma Diamond
- · 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 filling 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

H317 May cause an allergic skin reaction. Skin Sens. 1

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



GHS07

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

2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1ethanediyl) ester

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate 2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester triethylen glycol dimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment. P273 P280 Wear protective gloves / eye protection.

Wear protective clothing.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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· 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: -

Description.		
· Dangerous components:		
CAS: 861437-11-8	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 - diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥5-≤10%
Index number: 607-134-00-4	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	≥2.5-≤5%
CAS: 945656-78-0	2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl)bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥2.5-≤5%
CAS: 109-16-0 EINECS: 203-652-6 Index number: 607-134-00-4 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	<i>≥</i> 1- <i>≤</i> 5%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%

[·] 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.

If skin irritation or rash occurs: Get medical advice/attention.

- · 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.

In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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· **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. Use fire fighting measures that suit the environment.

• 5.2 Special hazards arising from the substance or mixture
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 Not required.
- 6.2 Environmental precautions: Do not allow to enter drainage system, surface or ground water.
- 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.

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SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
 - Information about protection against explosions and fires: No special measures required.
- · 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 °C).
- · 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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Not required.

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· DN			
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
Oral		-	0.3 mg/Kg (not defined)
Dermal	worker industrial, long te	rm, systemic	1.3 mg/Kg/d (not defined)
			0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long te	rm, systemic	3.3 mg/m3 (not defined)
	general population, long	term, systemic	0.6 mg/m3 (not defined)
109-16-0	triethylen glycol dimetha	acrylate	
Oral	general population, long	term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long te	rm, systemic	13.9 mg/Kg/d (not defined)
	general population, long	term, systemic	8.33 mg/Kg/d (not defined)
Inhalative	worker industrial, long te	rm, systemic	48.5 mg/m3 (not defined)
	general population, long	term, systemic	14.5 mg/m3 (not defined)
131-57-7	Oxybenzone	-	
Oral	general population, long	term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long te	rm, systemic	39 mg/Kg/d (not defined)
	general population, long	term, systemic	20 mg/Kg/d (not defined)
Inhalative	worker industrial, long te	rm, systemic	27.7 mg/m3 (not defined)
	general population, long term, systemic		6.0 may/m2 (mat datinad)
	gonoral population, long	terrii, systerriic	6.8 mg/m3 (not defined)
· PNI	, , , , , , , , , , , , , , , , , , ,	terrii, systerriic	6.8 mg/m3 (not defined)
	ECs	· •	,
	ECs 4 7,7,9(or 7,9,9)-trime bismethacrylate	· •	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d
72869-86-	ECs 47,7,9(or 7,9,9)-trime bismethacrylate	thyl-4,13-dio	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d
72869-86 -freshwater marine wa	ECs 47,7,9(or 7,9,9)-trime bismethacrylate	thyl-4,13-dio 0.01 mg/l (not	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d defined) ot defined)
72869-86- freshwater marine wa sewage tr	ECs 4 7,7,9(or 7,9,9)-trime bismethacrylate r ater	0.01 mg/l (not 0.001 mg/l (not	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d defined) of defined) defined)
72869-86- freshwater marine wa sewage tra sediment,	ECs 4 7,7,9(or 7,9,9)-trime bismethacrylate r ster eatment plant	0.01 mg/l (not 0.001 mg/l (not 0.001 mg/l (not 3.61 mg/l (not 4.56 mg/Kg (n	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d defined) of defined) defined) of defined)
72869-86- freshwater marine wa sewage tra sediment,	ECs 47,7,9(or 7,9,9)-trime bismethacrylate r ater eatment plant dry weight, freshwater dry weight, marine water	0.01 mg/l (not 0.001 mg/l (not 0.001 mg/l (not 3.61 mg/l (not 4.56 mg/Kg (n	xo-3,14-dioxa-5,12-diazahexadecane-1,16-d defined) of defined) defined) of defined) of defined)
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sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 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

Instantly remove any soiled and impregnated garments. Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not necessary if room is well-ventilated.
- · Hand protection

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 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 stateColour:Smell:FluidWhiteOdourless

· Odour threshold: Not determined. · Melting point/freezing point: Not determined

Boiling point or initial boiling point and

boiling range >300 °C
• Flammability Not applicable.

Lower and upper explosion limit
Lower: Not determined.
Upper: Not determined.

• Flash point: >150 °C (109-16-0 triethylen glycol dimethacrylate)

• **Decomposition temperature:** Not determined.

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	(Contd. of page
SADT	
· Ha	Not determined.
· Viscosity:	
Kinematic viscosity	Not determined.
· Kinematic viscosity	
dynamic:	Not determined.
Solubility	
Water:	Not miscible or difficult to mix
Partition coefficient n-octanol/water (log	
value)	Not determined.
· Steam pressure:	Not determined.
· Vapour pressure:	
Density and/or relative density	
· Density at 20 °C	2.23 g/cm³
Relative density	Not determined.
· Vapour density	Not determined.
<u> </u>	
	No further relevant information available.
· Appearance:	_ ,
Form:	Pasty
Important information on protection of heal	th
and environment, and on safety.	
Self-inflammability:	Product is not selfigniting.
Explosive properties:	Product is not explosive.
· Change in condition	
Evaporation rate	Not determined.
Information with regard to physical haza	rd
classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· 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	Void
· Corrosive to metals	Void
· Desensitised explosives	Void
Ecocholidea explosives	V OIU



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SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 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.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None

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 classific	ation:
--------------------------------------------------	--------

861437-11-8 2-Propenoic	acid,	(octah)	ydro-4,	7-metha	no-1H-indene-5	-diyl)
bis(methyleneimi						• ,

Oral LD50 >2,000 mg/kg (rat)

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)
Daws - 1	1050	> 0 000 man/len (mat) (OFCD 400

Dermal | LD50 | >2,000 mg/kg (rat) (OECD 402)

109-16-0 triethylen glycol dimethacrylate

Oral	LD50	8,300	mg/	kg ((rat)
------	------	-------	-----	------	-------

Dermal LD50 >2,000 mg/kg (mouse)

131-57-7 Oxybenzone

Oral | LD50 | >12,800 mg/kg (rat) (OECD 401)

Dermal LD50 >16,000 mg/kg (rabbit) (OECD 402)

- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · 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 Based on available data, the classification criteria are not met.
- 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.

GB



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12.1 Toxicity	12: Ecological information
· Aquatic to	
65997-17-3 G	•
	•
	>1,000 mg/l (fish)
	>1,000 mg/l (algae)
	1,000 mg/l (algae)
1102077211	1,000 mg/l (daphnia)
	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diy
EC50/48h	bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester
	24.9 mg/l (daphnia) ,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-di
b	ismethacrylate
	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
	>0.68 mg/l (algae) (OECD 201)
	0.21 mg/l (algae) (OECD 201)
	thylen glycol dimethacrylate
	51.9 mg/L (daphnia) (OECD 211)
	32 mg/l (daphnia) (OECD 211)
	>100 mg/l (algae) (OECD 201)
	18.6 mg/l (algae) (OECD 201)
EbC50 / 72h	72.8 mg/l (algae) (OECD 201)
131-57-7 Oxy	
LC50/96h	3.8 mg/l (fish) (OECD 203)
	0.67 mg/l (algae) (OECD 201)
	0.18 mg/l (algae) (OECD 201)
	0.72 mg/l (fish) (OECD 203)
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)
12.2 Persiste	ence and degradability
	,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-di ismethacrylate
Biodegradatio	on 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
	thylen glycol dimethacrylate
Biodegradation	on 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
131-57-7 Oxy	/benzone
Biodegradation	on 60-70 % /28d (not defined)
	(Contd. on pa



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· 12.3 Bioaccumulative potential

131-57-7 Oxybenzone

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

- · 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

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.
 - · Recommended cleaning agent: Water, if necessary with cleaning agent.

SECTION 14: Transport information	on	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	Void	
· 14.2 UN proper shipping name · ADR · ADN, IMDG, IATA	Void Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
· 14.4 Packing group · ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according instruments	g to IMO Not applicable.	

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- · Transport/Additional information:
- UN "Model Regulation": Void

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - Directive 2012/18/EU
 - Named dangerous substances ANNEX I 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

H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

Harmful to aquatic life with long lasting effects.

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

ADR: Accord relatir au transport international des marchandises dangereuses par 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 Sequing (division of the American Chemical Society)

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (UK REACH)

PNEC: Predicted No-Effect Concentration (ÚK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
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.