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

Printing date 25.11.2022 Version number 1 Revision: 25.11.2022

# SECTION 1: Identification of the substance/mixture and of the company/ undertakina

- · 1.1 Product identifier
  - · Trade name: Charisma Bulk Flow ONE
- · 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

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.

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:

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

triethylen glycol dimethacrylate

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

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

P280 Wear protective clothing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing. If skin irritation or rash occurs: Get medical advice/attention.

P333+P313

P337+P313 If eye irritation persists: Get medical advice/attention.

· 2.3 Other hazards -

Results of PBT and vPvB assessment

· **PBT:** Not applicable.

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· vPvB: Not applicable.

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# SECTION 3: Composition/information on ingredients

#### · 3.2 Mixtures

· Description: -

Description.		
<ul> <li>Dangerous components:</li> </ul>		
CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-xxxx	bisphenol A polyethnylene glycol diether dimethacrylate Aquatic Chronic 4, H413	≥10-<25%
CAS: 72869-86-4 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%
CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥0.1-<1%
CAS: 21245-02-3 EINECS: 244-289-3 Reg.nr.: 01-2120766649-35- XXXX	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	<0.3%

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 if skin irritation continues, consult a doctor.
  - After eve 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 Allergic reactions
- 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.

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- · 5.2 Special hazards arising from the substance or mixture
- No further relevant information available.
- · 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: Prevent material from reaching sewage system, holes and cellars.
- 6.3 Methods and material for containment and cleaning up: Collect mechanically.
- · 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

No special measures required.

Ensure good ventilation/exhaustion at the workplace.

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 under dry conditions.
- · 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.

juli 6u.			
ELs			
1 bisphenol A polyethnylene glycol di	ether dimethacrylate		
general population, long term, systemic	5 mg/Kg (not defined)		
worker industrial, long term, systemic	140 mg/Kg/d (not defined)		
general population, long term, systemic	50 mg/Kg/d (not defined)		
worker industrial, long term, systemic	98.7 mg/m3 (not defined)		
general population, long term, systemic	17.4 mg/m3 (not defined)		
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl			
•			
general population, long term, systemic	0.3 mg/Kg (not defined)		
	TLS  1 bisphenol A polyethnylene glycol di general population, long term, systemic worker industrial, long term, systemic general population, long term, systemic worker industrial, long term, systemic general population, long term, systemic		

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				(Contd. of page 3)
Dermal	worker industrial, long te	rm, systemic	1.3 mg/Kg/d (not defined)	
	general population, long	-	· · · · · · · · · · · · · · · · · · ·	
Inhalative	worker industrial, long te	rm, systemic	3.3 mg/m3 (not defined)	
	general population, long	term, systemic	0.6 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	6.8 mg/m3 (not defined)	
109-16-0 t	riethylen 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)	
· PNI	Cs			
72869-86-	4 7,7,9(or 7,9,9)-trimet	hyl-4,13-dioxo	o-3,14-dioxa-5,12-diazahexadeca	ne-1,16-diyl
	bismethacrylate	-		, ,
freshwater	•	0.01 mg/l (not	•	
marine wa	ter	0.001 mg/l (no	•	
sewage tre	eatment plant	3.61 mg/l (not	defined)	
sediment,	dry weight, freshwater	4.56 mg/Kg (n	ot defined)	
sediment, dry weight, marine water		0.46 mg/Kg (not defined)		
soil, dry weight		0.91 mg/Kg (n	ot defined)	
	Oxybenzone			
freshwater	•	0.00067 mg/l (	•	
marine wa		0.000067 mg/l	,	
-	eatment plant	10 mg/l (not de	,	
	dry weight, freshwater	0.066 mg/Kg (l		
sediment,	dry weight, marine water	0.007 mg/Kg (i	not defined)	
soil, dry w	_	0.013 mg/Kg (i	not defined)	
109-16-0 t	riethylen glycol dimetha			
freshwater	•	0.016 mg/l (no	•	
marine wa		0.002 mg/l (no	•	
-	eatment plant	1.7 mg/l (not d		
	dry weight, freshwater	0.185 mg/Kg (i	•	
	dry weight, marine water		•	
soil, dry w	eight	0.027 mg/Kg (l	not defined)	

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

# · 8.2 Exposure controls

- · Individual protection measures, such as personal protective equipment
  · General protective and hygienic measures

  Wash hands during breaks and at the end of the work.
  · Breathing equipment: Not necessary if room is well-ventilated.

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· 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

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 · Colour: Whitish · Smell: Odourless Odour threshold:

• Melting point/freezing point:

Boiling point or initial boiling point and

boiling range

· Flammability

· Flash point:

· Lower and upper explosion limit

Lower: Upper:

· Decomposition temperature:

SADT pН

Viscosity:

Kinematic viscosity

dynamic:

Solubility Water:

Partition coefficient n-octanol/water (log

value) Steam pressure:

Not determined. Not determined

140 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)

Not applicable.

Not determined. Not determined.

>100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-

1,16-diyl bismethacrylate)

Not determined.

Not determined.

Not determined. Not determined.

Not miscible or difficult to mix

Not determined. Not determined.

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

• 9.2 Other information No further relevant information available.

Appearance:

Form: Pasty

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

• Self-inflammability:
• Explosive properties:

Product is not selfigniting.
Product is not explosive.
Not determined.

Change in condition

· Evaporation rate Not determined.

# · Information with regard to physical hazard classes

43363	
· 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

# SECTION 10: Stability and reactivity

· Desensitised explosives

- · 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.

Void

- · 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.

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· L	D/LC5	0 values that are relevant for classification:
41637-3	38-1 bi	sphenol A polyethnylene glycol diether dimethacrylate
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
72869-8		7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl smethacrylate
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
131-57-	7 Oxyl	penzone
Oral	LD50	>12,800 mg/kg (rat) (OECD 401)
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)
109-16-	0 trietl	nylen glycol dimethacrylate
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)
21245-0	)2-3 2-	ethylhexyl 4-(dimethylamino)benzoate
Oral	LD50	14,900 mg/kg (rat)
		sion/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.

# 21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate

Oral NOAEL (Fertility) 50 mg/kg/d /64 d (rat) (OECD 421)

- 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

· Endoc	rine disrupting properties	
131-57-7	Oxybenzone	List II
128-37-0	2,6-di-tert-butyl-p-cresol	List II

### **SECTION 12: Ecological information**

· Aquatic t	oxicity:	
41637-38-1 k	isphenol A polyethnylene glycol diether dimethacrylate	
EC50/72h	>100 mg/l (algae) (OECD 201)	
LL50/96h	>100 mg/L (fish) (OECD 203)	
EL50/48h	>100 mg/L (daphnia) (OECD 202)	
EL50/72h	>100 mg/L (algae) (OECD 201)	
NOEC / 21d	≥22.4 mg/l (daphnia) (OECD 211)	
NOEC 28d	14.3 mg/l (bacteria)	
NOELR	100 mg/L /48h (daphnia) (OECD 202)	
		(Contd. on page 8



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72869-86-4 7	Contd. of page 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy
b	ismethacrylate
EC50/48h	>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)
131-57-7 Oxy	/benzone
EC50/48h	1.87 mg/l (daphnia) (OECD 202)
LC50/96h	3.8 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)
NOEC / 72h	0.18 mg/l (algae) (OECD 201)
NOEC / 96h	0.72 mg/l (fish) (OECD 203)
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)
109-16-0 trie	thylen glycol dimethacrylate
EC50/21d	51.9 mg/L (daphnia) (OECD 211)
LC50/96h	16.4 mg/l (fish) (OECD 203)
NOEC / 21d	32 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>100 mg/l (algae) (OECD 201)
NOEC / 72h	18.6 mg/l (algae) (OECD 201)
EbC50 / 72h	72.8 mg/l (algae) (OECD 201)
12.2 Persiste	ence and degradability
	isphenol A polyethnylene glycol diether dimethacrylate
Biodegradation	on 24 % /28d (not defined) (OECD 301D)
b	,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy ismethacrylate
Biodegradation	on 22 % /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)
109-16-0 trie	thylen glycol dimethacrylate
Biodegradation	on 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
ี่ 12.3 Bioaccเ	imulative potential
131-57-7 Oxy	/benzone
	tion factor (BCF)   >33-<160 (fish) (OECD 305)
	in a il Na findhan valariant information a reilala

• 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: Avoid transfer into the environment.



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# 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.

Disposal must be made according to official regulations.

- Uncleaned packagings:
  - · Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

SECTION 14: Transport information	on	
· 14.1 UN number or ID number · ADR, IMDG, IATA	Void	
14.2 UN proper shipping name ADR, IMDG, IATA	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 IMO instruments	<b>g to</b> Not applicable.	
· 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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

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Causes serious eye irritation.

H335 May cause respiratory irritation.

H360 May damage fertility or the unborn child.

H400 Very toxic to aquatic life.

Toxic to aquatic life with long lasting effects. H411

May cause long lasting harmful effects to aquatic life. 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 Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals GHS: Globally Harmonised System of Classification and Labelling of Chemical 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 Page Services and Service Programment PBT: Persistent and year Bioaccumulative

vPvB: very Persistent and very Bioaccumulative Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1: Skin sensitisation — Category 1
Skin Sens. 1B: Skin sensitisation — Category 1B
Repr. 1B: Reproductive toxicity — Category 1B
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 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
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard — Category 4

\* Data compared to the previous version altered.