

Page 1/11

Tel: +61 (02) 9153 0311

### Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Hazardous according to criteria of Australian Safety and Compensation Council.

#### 1 Identification

- · Other means of identification
  - · *Trade name:* Charisma
  - · 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
- · Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:

Kulzer Australia Pty Ltd Unit 20, 53 Lorraine St PEAKHURST NSW 2210 Australia

· Informing department: see above Emergency telephone number:

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

### 2 Hazard(s) Identification

Classification of the substance or mixture

Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.

- · Label elements
  - GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS07

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

triethylen glycol dimethacrylate (≥1-≤5 %)

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

Hazard statements

May cause an allergic skin reaction.

Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves.
IF ON SKIN: Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

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

Specific treatment (see on this label).

Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)



Page 2/11

## Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 1)

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

## 3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
  - · **Description**: Product based on methacrylates

_	· Dangerous components:	
109-16-0		<i>≥</i> 1- <i>≤</i> 5%
	Skin sensitisation – Category 1B, H317	
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	<i>≥</i> 1- <i>≤</i> 5%
	Skin sensitisation – Category 1B, H317	

<sup>·</sup> Additional information For the wording of the listed hazard phrases refer to section 16.

#### 4 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.
- After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

- Information for doctor
  - · Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## 5 Fire Fighting Measures

· 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.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Protective equipment: No special measures required.
- · Additional information -

#### 6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:

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

(Contd. on page 3)



Page 3/11

(Contd. of page 2)

## Safety Data Sheet according to WHS Regulations

 Date of issue: 18.03.2025
 Version number 5
 Revision: 18.03.2025

Trade name: Charisma

· Reference to other sections

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

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## 7 Handling and Storage

- · Handling
  - · Precautions for safe handling No special measures required.
  - · Information about protection against explosions and fires: No special measures required.
- · 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).
- · Specific end use(s) No further relevant information available.

## 8 Exposure controls and personal protection

- · Appropriate engineering controls No further data; see section 7.
- 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.

· DNI	ELs	
109-16-0 1	riethylen glycol dimethacrylate	
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)
	general population, long term, systemic	14.5 mg/m3 (not defined)
72869-86-	4 7,7,9(or 7,9,9)-trimethyl-4,13-diox bismethacrylate	o-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
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	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 mg/m3 (not defined)
79-41-4 m	ethacrylic acid	
Dermal	worker industrial, long term, systemic	4.25 mg/Kg/d (not defined)
	general population, long term, systemic	2.55 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, local	88 mg/m3 (not defined)
	worker professional, long term, systemic	29.6 mg/m3 (not defined)
	general population, long term, systemic	6.3 mg/m3 (not defined)
		(Contd. on page 4)

page 4



Page 4/11

## Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

		(Contd. of page 3)
general population, long	term, local	6.55 mg/m3 (not defined)
·PNECs		
109-16-0 triethylen glycol dimetha	acrylate	
freshwater	0.016 mg/l (not	defined)
marine water	0.002 mg/l (not	defined)
sewage treatment plant	1.7 mg/l (not de	fined)
sediment, dry weight, freshwater	0.185 mg/Kg (n	ot defined)
sediment, dry weight, marine water	0.018 mg/Kg (n	ot defined)
soil, dry weight	0.027 mg/Kg (not defined)	
72869-86-4 7,7,9(or 7,9,9)-trime bismethacrylate	thyl-4,13-diox	o-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
freshwater	0.01 mg/l (not d	lefined)
marine water	0.001 mg/l (not	defined)
sewage treatment plant	3.61 mg/l (not d	lefined)
sediment, dry weight, freshwater	4.56 mg/Kg (no	t defined)
sediment, dry weight, marine water	0.46 mg/Kg (no	t defined)
soil, dry weight	0.91 mg/Kg (no	t defined)

- · Additional information: The lists that were valid during the compilation were used as basis.
- · Personal protective equipment
  - General protective and hygienic measures Wash hands during breaks and at the end of the work.
  - Breathing equipment: Not required.
  - · Protection of hands:

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: not absolutely neccessary
- · Body protection: Light weight protective clothing

#### 9 Physical and Chemical Properties

- · General Information
  - · Appearance:
    - · **Form:** Pasty

(Contd. on page 5)



Page 5/11

## Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 4)

· Colour: Different according to colour

• Smell: Odourless
• Odour threshold: Not determined.
pH-value: Not determined.

Change in condition

· Melting point/freezing point: Not determined · Initial boiling point and boiling range: Not determined

· Flash point: >100 °C

Inflammability (solid, gaseous)
Decomposition temperature:
Self-inflammability:
Explosive properties:
Not applicable.
Not determined.
Product is not selfigniting.
Product is not explosive.

· Critical values for explosion:

Lower:
Upper:
Not determined.
Not determined.
Not determined.
Not determined.
Not determined
Not determined
Not determined
Not determined.
Not determined.
Not determined.
Not determined.
Not determined.
Not determined.

· Solubility in / Miscibility with

• Water: Not miscible or difficult to mix

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

· dynamic: Not determined. · kinematic: Not determined.

Other information No further relevant information available.

• Particle characteristics Not applicable.

Physical state Liquid

### 10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Conditions to be avoided: No decomposition if used and stored according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None
- · Additional information:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

#### 11 Toxicological Information

· Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

(Contd. on page 6)



Page 6/11

## Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

		(Contd. of page 5)
· LD/	LC50 valu	es that are relevant for classification:
65997-18-	4 frits, ch	emicals
Oral	LD50	>2000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
(1-methyl	ethylidene	e)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
Oral	LD50	>5000 mg/kg (rat)
109-16-0	triethylen	glycol dimethacrylate
Oral	LD50	8300 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)
72869-86-		r 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl acrylate
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
79-41-4 m	ethacrylic	acid
Oral	LD50	1320 mg/kg (rat) (OECD 401)
Dermal	LD50	500-1000 mg/kg (rab)
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)

- · Primary irritant effect:
  - 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.

## 12 Ecological Information

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•	Ta	XİC	Itv	

TOXICITY	
· Aquatic t	
65997-18-4 f	rits, chemicals
LC50/96h	≥3.09 mg/l (fish)
ErC50 / 72 h	≥2.4 mg/l (algae)
65997-17-3 (	Glaspulver
EC50/72h	>1000 mg/l (daphnia)
LC50/96h	>1000 mg/l (fish)
ErC50 / 72 h	>1000 mg/l (algae)
NOEC / 72h	1000 mg/l (algae)
	1000 mg/l (daphnia)
	(Contd. on page

(Contd. on page



Page 7/11

# Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

	(Contd. of page 6)
(1-methyleth	nylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
LC50/96h	>100 mg/l (fish) (OECD 203)
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)
72869-86-4 7 b	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl pismethacrylate
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)
79-41-4 metl	nacrylic acid
EC50/48h	>130 mg/l (daphnia) (EPA OTS 797.1300)
LC50/96h	85 mg/l (fish) (EPA OTS 797.1400)
NOEC / 21d	53 mg/l (daphnia)
ErC50 / 72 h	45 mg/l (algae) (OECD 201)
NOEC / 72h	8.2 mg/l (algae) (OECD 201)
NOEC / 96h	12 mg/l (fish) (EPA OTS 797.1400)
NOEC / 48h	130 mg/l (daphnia) (EPA OTS 797.1300)
	and degradability
	nylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
	on 21 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)
	thylen glycol dimethacrylate
_	on 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
h	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl pismethacrylate
	on 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
	hacrylic acid
	on 86 % /28d (not defined) (OECD 301D)

- Behaviour in environmental systems:
  Bioaccumulative potential No further relevant information available.
  - · Mobility in soil No further relevant information available.
- · Additional ecological information:

• **General notes:**Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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

(Contd. on page 8)



Page 8/11

## Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 7)

· **vPvB:** Not applicable.

· Other adverse effects No further relevant information available.

### 13 Disposal considerations

- · Waste treatment methods
  - Recommendation

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage.

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.

UN-Number		
· ADG, ADN, IMDG, IATA	Void	
UN proper shipping name · ADG, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	Void	
Packing group · ADG, IMDG, IATA	Void	
Environmental hazards: • Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex Marpol and the IBC Code	II of Not applicable.	
Transport/Additional information:	-	
UN "Model Regulation":	Void	

### 15 Regulatory information

 $\cdot$  Safety, health and environmental regulations/legislation specific for the substance or mixture

· Australian Inventory of Industrial Chemicals

65997-17-3 Glaspulver

65997-18-4 frits, chemicals

(Contd. on page 9)



Page 9/11

# Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

	(Contd. of page 8) (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
68476-25-5	Feldspar-group minerals
	triethylen glycol dimethacrylate
	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
7732-18-5	water, distilled, conductivity or of similar purity
112945-52-5	Amorphous silica
	water, distilled, conductivity or of similar purity
	Quartz (SiO2)
4948-15-6	C.I. Pigment Red 149
68186-88-9	Zinc iron chromite brown spinel
	Kupfer-, Chrom-, Eisenoxid-Spinell
	titanium dioxide
	Oxybenzone
7775-14-6	sodium dithionite
	2-ethylhexyl 4-(dimethylamino)benzoate
10373-78-1	dl-bornane-2,3-dione
	methyl methacrylate
	ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate
64-19-7	acetic acid
	2,6-di-tert-butyl-p-cresol
	tert-butyl peroxy(2-ethylhexanoate)
	propylidynetrimethanol
	2- (2H-Benzotriazol-2-yl) -p-cresol
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
	lia: Priority Existing Chemicals
None of the in	ngredients is listed.

#### · Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

### · Regulation (EU) No 649/2012

None of the ingredients are included.

### · National regulations

The product is subject to classification in accordance with the prevailing version of the regulations on hazardous materials.

#### Other regulations, limitations and prohibitive regulations

AICS - Australian Inventory of Chemical Substances	
65997-17-3	Glaspulver
65997-18-4	frits, chemicals

(Contd. on page 10)



Page 10/11

## Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

	(Contd. of pag (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
68476-25-5	Feldspar-group minerals
	triethylen glycol dimethacrylate
	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-di bismethacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
7732-18-5	water, distilled, conductivity or of similar purity
112945-52-5	Amorphous silica
7732-18-5	water, distilled, conductivity or of similar purity
14808-60-7	Quartz (SiO2)
4948-15-6	C.I. Pigment Red 149
68186-88-9	Zinc iron chromite brown spinel
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
	Chrome Antimony Titanate
13463-67-7	titanium dioxide
131-57-7	Oxybenzone
7775-14-6	sodium dithionite
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate
10373-78-1	dl-bornane-2,3-dione
80-62-6	methyl methacrylate
	Diethyl-(2,5-dihydroxyterephthalat)
84434-11-7	ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate
64-19-7	acetic acid
128-37-0	2,6-di-tert-butyl-p-cresol
	tert-butyl peroxy(2-ethylhexanoate)
77-99-6	propylidynetrimethanol
	2- (2H-Benzotriazol-2-yl) -p-cresol
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

#### 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.

Abbreviations and acronyms:

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

INDG. International Mantime Code for Danigerous Goods
IATA: International Air Transport Association
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)

(Contd. on page 11)



Page 11/11

# Safety Data Sheet according to WHS Regulations

Date of issue: 18.03.2025 Version number 5 Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 10)

DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent LC50: Letnal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin sensitisation – Category 1: Skin sensitisation – Category 1
Skin sensitisation – Category 1B: Skin sensitisation – Category 1B
\* Data compared to the previous version altered.