SAFETY DATA SHEETS

This SDS packet was issued with item:

071455963

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071495639 071495647

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071455849 071455856 071455864 071455872 071455880 071455955 071455971 071455989 071455997 071456003 071456011 071456029 077083538 077126188 077126196 077126204 077126212 077126238 077126246 077126253 077126261 077126279 077126287 077126295 077126303 077126311 077126329 077126337 077126345 077126352 077126360 077126378 077126386 077126394 077126402 077126410 077126428 077126436 077126444 077126451 077126550 077126568 077126576 077126584 077126592 077126600 077126618 077126626 077126634 077126642 077126659 077126667 077126675 077126683 077126691 077126709 077126717 077126725 077126733 077126741 077126758 077126766 077126774 077142540 077142581 077142599 077142607 077142904 077142961 077143001 077143043 077143084 077143241 077143266 077143282 077143290 077143316 077143324 077143340 077143365 077143381 077143407 077143423

ivoclar vıvadenl:

Safety Data Sheet acc. to OSHA HCS

Printing date 07/22/2019

Version number 8

Reviewed on 06/03/2019

1 Identification

- · Product identifier
- · Trade name: Tetric EvoCeram

· Application of the substance / the mixture Light-curing resin-based dental restorative material

Details of the supplier of the safety data sheet
Manufacturer/Supplier: Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228 USA Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada Phone: +1 905 670 8499 Fax: +1 905 670 3102

 Information department: Quality Assurance / Regulatory Affairs
 Emergency telephone number: 24 Hour Emergency Assistance: Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

Skin Irrit. 2H315Causes skin irritation.Eye Irrit. 2AH319Causes serious eye irritation.Skin Sens. 1H317May cause an allergic skin reaction.

- · Label elements
- *GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS).*
- · Hazard pictograms



· Signal word Warning

Hazard-determining components of labeling: urethane dimethacrylate Bis-GMA
Hazard statements Causes skin irritation. Causes serious eye irritation.

(Contd. on page 2)

US

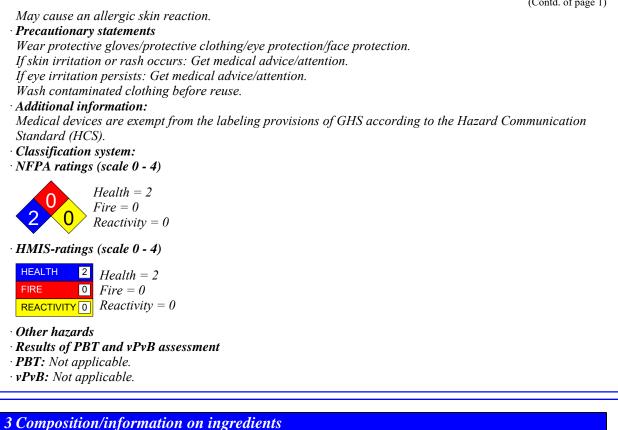
Version number 8

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Trade name: Tetric EvoCeram

(Contd. of page 1)



· Chemical characterization: Mixtures

• Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous	components:
-------------	-------------

2 mger om comp		
CAS: 72869-86-4	urethane dimethacrylate	≥2.5-<10%
CAS: 36425-15-7	Bis-GMA	≥2.5-<10%
CAS: 13760-80-0	ytterbium trifluoride	≥2.5-<10%

4 First-aid measures

· Description of first aid measures

• After inhalation:

Supply fresh air and to be sure call for a doctor.

- In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Rinse with water.

· After eye contact:

- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: If symptoms persist 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.

(Contd. on page 3)

Version number 8

Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

(Contd. of page 2)

5 *Fire-fighting measures*

· Extinguishing media

• Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

• Special hazards arising from the substance or mixture No further relevant information available.

• Advice for firefighters

· Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.

· 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 disposal information.

7 Handling and storage

· Handling:

• *Precautions for safe handling* Only adequately trained personnel should handle this product. For use in dentistry only.

• Information about protection against explosions and fires: No special measures required.

- Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- Protect from exposure to the light.
- Protect from heat and direct sunlight.

Keep receptacle tightly sealed.

Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

- · Control parameters
- · Components with limit 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.

• Additional information: The lists that were valid during the creation were used as basis.

- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Usual hygienic measures for dental practice and dental laboratories. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

⁻ US

Printing date 07/22/2019

Version number 8

Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

(Contd. of page 3)

• Breathing equipment: Not required.

• Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

• 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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. • *Eye protection: Safety glasses*

Information on basic physical and	chemical properties	
General Information		
Appearance:	2	
Form:	Pasty	
Color:	According to product specification	
Odor:	<i>Characteristic</i>	
Odor threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gaseous):	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapor pressure:	Not applicable.	
Density at 20 °C (68 °F):	2.1 g/cm ³ (17.525 lbs/gal)	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	

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Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

		(Contd. of pag
· Solubility in / Miscibility with	h	
Water:	Nearly insoluble.	
Partition coefficient (n-octar	nol/water): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
• Other information	No further relevant information available.	

10 Stability and reactivity

· Reactivity No further relevant information available.

• *Chemical stability Stable under normal handling and storage conditions.*

Photoreactive (Danger of polymerization).

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid

Keep away from heat and direct sunlight.

- Protect from exposure to the light.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

· Information on toxicological effects

- Acute toxicity:
- on the skin: No irritant effect.
- on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- Additional toxicological information: No further relevant information available.

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

· Toxicity

- Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- *Mobility in soil* No further relevant information available.
- Additional ecological information:

• General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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Printing date 07/22/2019

Version number 8

Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

(Contd. of page 5)

· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

· Other adverse effects No further relevant information available.

13 Disposal considerations

• Waste treatment methods

· Recommendation:

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· Uncleaned packagings:

• Recommendation: Disposal must be made according to official regulations.

4 Transport information	
· UN-Number · DOT, ADR/RID/ADN, ADN, IMDG, IA	TA Void
· UN proper shipping name · DOT, ADR/RID/ADN, ADN, IMDG, IA	TA Void
· Transport hazard class(es)	
· DOT, ADR/RID/ADN, ADN, IMDG, IA · Class	TA Void
· Packing group · DOT, ADR/RID/ADN, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex II MARPOL73/78 and the IBC Code	of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

• TSCA (Toxic Substances Control Act):

CAS: 72869-86-4 urethane dimethacrylate

CAS: 1565-94-2 Bis-GMA

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US

Version number 8

Reviewed on 06/03/2019

(Contd. of page 6)

Trade name: Tetric EvoCeram

CAS: 13760-80-0	ytterbium trifluoride

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

• Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

• Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

CAS: 13760-80-0 ytterbium trifluoride

A4

·NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS). • *Hazard pictograms*



· Signal word Warning

- Hazard-determining components of labeling: urethane dimethacrylate Bis-GMA
 Hazard statements Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.
- · Precautionary statements
- *Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or rash occurs: Get medical advice/attention.*
- *If eye irritation persists: Get medical advice/attention.*
- Wash contaminated clothing before reuse.
- · National regulations:
- Other regulations, limitations and prohibitive regulations
 Other regulations, limitations and prohibitive regulations
 The product is a medical device according to the Directive 93/42/EEC.
 This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.
 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

(Contd. on page 8)

Printing date 07/22/2019

Version number 8

Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

(Contd. of page 7)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Date of preparation / last revision 07/22/2019 / 7 • 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 DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A Skin Sens. 1: Skin sensitisation – Category 1 • * Data compared to the previous version altered.

ivoclar

Safety Data Sheet according to HPR, Schedule 1

Printing date 03/07/2024

Version number 9

Reviewed on 03/07/2024

1 Identification

- · Product identifier
- · Trade name: Tetric EvoCeram

· Application of the substance / the mixture Polymer-based dental restorative material (intraoral light-curing)

• Details of the supplier of the safety data sheet • Manufacturer/Supplier:

Ivoclar Vivadent Inc. 175 Pineview Drive, Amherst, N.Y. 14228 USA Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada Phone: +1 905 670 8499 Fax: +1 905 670 3102

· Information department: Quality Assurance / Regulatory Affairs

• Emergency telephone number: 24 Hour Emergency Assistance: Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard identification

· Classification of the substance or mixture

Eye Irritation - Category 2A H319 Causes serious eye irritation. Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

· Label elements

• *GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS).*

· Hazard pictograms



· Signal word Warning

- *Hazard-determining components of labeling: urethane dimethacrylate*
- · Hazard statements
- Causes serious eye irritation.
- May cause an allergic skin reaction.
- · Precautionary statements
- *Wear protective gloves/protective clothing/eye protection/face protection. If eye irritation persists: Get medical advice/attention.*

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Printing date 03/07/2024

Version number 9

Reviewed on 03/07/2024

Trade name: Tetric EvoCeram

(Contd. of page 1)

7-10% w/w

1-5% w/w *

Wash contaminated clothing before reuse.

• Classification system: • NFPA ratings (scale 0 - 4)

· HMIS-ratings (scale 0 - 4)

HEALTH 2	Health = 2
FIRE 0	Fire = 0
REACTIVITY 0	Reactivity = 0

3 Composition/Information on ingredients

· Chemical characterization: Mixtures

• Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 72869-86-4 urethane dimethacrylate

- CAS: 13760-80-0 ytterbium trifluoride
- * Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

· Description of first aid measures

· After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact: Rinse with water.

- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: If symptoms persist 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

- · Extinguishing media
- Suitable extinguishing agents:
- CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- *Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.*
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.

(Contd. on page 3)

CA

Printing date 03/07/2024

Version number 9

Reviewed on 03/07/2024

	Trade name: Tetric EvoCeram
	 Methods and material for containment and cleaning up: Pick up mechanically. Reference to other sections See Section 7 for information on safe handling. See Section 13 for information on personal protection equipment.
	7 Handling and storage
	 Handling: Precautions for safe handling Only adequately trained personnel should handle this product. For use in dentistry only. Information about protection against explosions and fires: No special measures required.
	 Conditions for safe storage, including any incompatibilities Storage: Storage: Requirements to be met by storerooms and receptacles: Store only in the original receptacle. Information about storage in one common storage facility: Not required. Further information about storage conditions: Protect from exposure to the light. Protect from heat and direct sunlight.
*	specific em asels) to jaranet recordination available. 8 Exposure controls/ Personal protection
	· Additional information about design of technical systems: No further data; see section 7.
	 Control parameters Components with limit values that require monitoring at the workplace: Components with limit 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. Additional information: The lists that were valid during the creation were used as basis.
	 Exposure controls Personal protective equipment: General protective and hygienic measures: Usual hygienic measures for dental practice and dental laboratories. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed. Breathing equipment: Not required.
	Protective gloves
	The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation The selection of the suitable aboves does not only deneed on the material but also on further marks of audity.
	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 (Conta on page 4)

CA

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Reviewed on 03/07/2024

Trade name: Tetric EvoCeram

(Contd. of page 3)

application.

*

• Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Not suitable are gloves made of the following materials:
- Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
- · Eye protection: Safety glasses

Physical and chemical properties	
Information on basic physical and	chemical properties
General Information	
Appearance:	
Form:	Pasty
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not applicable.
Density at 20 °C:	2.1 g/cm^3
Relative density	Not determined.
Vapor density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Nearly insoluble.
Partition coefficient (n-octanol/wat	ter): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Other information	No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability

Stable under normal handling and storage conditions.

(Contd. on page 5)

CA

Printing date 03/07/2024

Version number 9

Reviewed on 03/07/2024

Trade name: Tetric EvoCeram

(Contd. of page 4)

Photoreactive (Danger of polymerization).

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.

• Conditions to avoid

Keep away from heat and direct sunlight. Protect from exposure to the light.

• **Incompatible materials:** No further relevant information available.

• Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Specific symptoms in biological assay:
- on the skin: No irritant effect.
- on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- Additional toxicological information: No further relevant information available.

· Carcinogenic categories

·NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- *Persistence and degradability* No further relevant information available.
- Behavior in environmental systems:
- *Bioaccumulative potential* No further relevant information available.
- Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:
- Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

(Contd. on page 6)

Printing date 03/07/2024

Version number 9

Reviewed on 03/07/2024

Trade name: Tetric EvoCeram

(Contd. of page 5)

UN-Number	17 • 1
DOT/TDG, ADR, ADN, IMDG, IATA	Void
UN proper shipping name	
DOT/TDG, ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
DOT, ADR, ADN, IMDG, IATA	
Class	Void
Packing group	
DOT/TDG, ADR, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II	T of
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport
1 5	(ADR, IMDG, IATA).
UN "Model Regulation":	Void

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

• Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

• TSCA (Toxic Substances Control Act):

CAS: 13760-80-0 ytterbium trifluoride

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS). • *Hazard pictograms*



· Signal word Warning

· Hazard-determining components of labeling:

urethane dimethacrylate

· Hazard statements

Causes serious eye irritation. May cause an allergic skin reaction.

- May cause an allergic skin reac
- *Precautionary statements Wear protective gloves/protective clothing/eye protection/face protection.*

(Contd. on page 7)

C/

Printing date 03/07/2024

Version number 9

Reviewed on 03/07/2024

Trade name: Tetric EvoCeram

(Contd. of page 6)

If eye irritation persists: Get medical advice/attention. Wash contaminated clothing before reuse.

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR). This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Contact:

• Date of the latest revision of the safety data sheet 03/07/2024

• Abbreviations and acronyms:

IMO: International Maritime Organization

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

• * Data compared to the previous version altered.

CA -