## **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

077126717

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

071487552 071487560 071487610 071487628 071487636 071487644 071487651 071487685 071487693 071487719 071487727 071487743 071487750 071487768 071487776 071487784 071487800 071487818 071495639 071495647 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 077126683 077126691 077126709 077126725 077126733 077126741 077126758 077126766 077126774 077142516 077142540 077142557 077142565 077142573 077142599 077142607 077142615 077142623 077142631 077142649 077142656 077142698 077142706 077142714 077142722 077142730 077142904 077142912 077142920 077142938 077142946 077142953 077142961 077142979 077142987 077142995 077143011 077143019 077143027 077143035 077143043 077143050 077143068 077143076 077143084 077143092 077143217 077143241 077143258 077143365 077143284 077143282 077143399 077143308 077143316 077143423 077143431 077143355 077143355 077143381 077143399 077143407 077143415 077143423 077143431 077143555

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).

077083538

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

MSDS Name: Tetric EvoCeram

Manufacturer Name: Ivoclar/Vivadent

Address:

175 Pineview Drive,

AMHERST NY 14228

2785 Skymark Ave. Unit 1, Mississauga, Ontario L4W 4Y3

For emergency only call INFOTRAC: 1-800-535-5053

In Canada, call CANUTEC: 613-996-6666

Manufacturer MSDS Revision Date:

November 18, 2004

General Use:

Light Curing low-shrinkage Dental Restorative

FOR PROFESSIONAL DENTAL USE ONLY.

Product Identification: Light Curing low-shrinkage Dental Restorative

Product Codes:

590284 - 590291, 590293 - 590349

\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 2 : Hazardous Ingredients/Identity Information

\*\*\*\*\*\*\*\*\*\*\*\*\*

Chemical Name Bis-GMA CAS# 1565-94-2 Percent 5-10%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Hazardous: Yes

LD50/LC50/TDLo: Not Available

Chemical Name

Ethoxylated Bis-EMA CAS#

41637-38-1 Percent

1-5%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Hazardous: Yes

LD50/LC50/TDLo: Not Available

Chemical Name

Urethane dimethacrylate CAS# 72869-86-4 Percent 5-10%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Hazardous: Yes

LD50/LC50/TDLo: Not Available Chemical Name Barium glass filler, silanised CAS# Not Available Percent 30-40%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Comments:

Other Ingredient

LD50/LC50/TDLo: Not Available Chemical Name Ytterbiumtrifluoride CAS# 1376-08-0 Percent 1-5%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Comments:

Other Ingredient

LD50/LC50/TDLo: Not Available Chemical Name Mixed oxide, silanised Not Available Percent 5-10%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Comments:

Other Ingredient

LD50/LC50/TDLo: Not Available Chemical Name Copolymer CAS# Not Available Percent 30-40%

OSHA PEL TWA: \*Not Available ACGIH TLV TWA: \*Not Available

Comments:

Other Ingredient

LD50/LC50/TDLo: Not Available Comments:

\*All Exposure limits are in milligram per cubic meter of air (mg/m3)

LD-50 (oral rat): > 5000 mg/kg

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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Physical State/Appearance:
 Paste
Color:
 Off white to cream colored
Odor:
No odor
: Hq
Not Determined
Vapor Pressure:
mm Hg: Not Applicable
Vapor Density:
Air = 1: Not Applicable
Boiling Point:
 Deg C: Not Applicable
Melting Point:
 Deg C: Not Applicable
Solubility:
 In water: < 0.1%
Specific Gravity:
 (H2O = 1 \text{ g/cm}3): 2.09 - 2.14 \text{ g/cm}3 (20 \text{ deg C})
Odor Threshold:
None
FlashPoint:
 > 150 deg C
Auto Ignition Temp:
 Deg C: Not Applicable
Upper Flammable Explosive Limit:
 % In Air: Not Applicable
Lower Flammable Explosive Limit:
 % In Air: Not Applicable
*****************
SECTION 4 : Fire And Explosion Hazards
****************
Flash Point:
 > 150 deg C
Upper Flammable or Explosive Limit: % In Air: Not Applicable
Lower Flammable or Explosive Limit: % In Air: Not Applicable
Auto Ignition Temperature: Deg C: Not Applicable
Extinguishing Media:
 Water fog, carbon dioxide, foam, dry chemicals
Hazardous Combustion Byproducts:
Unusual Fire Hazards:
None
****************
SECTION 5 : Health Hazards
***************
Applies to All Ingredients:
Aggravation of Pre-Existing Conditions:
 Resin Allergies
Applies to all ingredients:
Routes of Exposure:
 Ingestion, inhalation, eyes
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Ingestion Effects:
 Symptoms of Acute Exposure:
The LD-50 (oral rat) for Tetric EvoCeram is > 5000 mg/kg.
Chronic Skin Effects:
 Symptoms of Chronic Exposure:
Prolonged or frequently repeated skin contact with the uncured material
may cause allergic skin reactions.
Carcinogenicity:
 Potential Carcinogen: No
NTP: No
IARC: No
OSHA Req.: No
Teratogenicity:
No
Embryo Toxicity:
Sensitization:
No
Reproductive Toxicity:
Bis-GMA:
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
Ethoxylated Bis-EMA:
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
Urethane dimethacrylate:
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
Barium glass filler, silanised:
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
Ytterbiumtrifluoride :
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
Mixed oxide, silanised:
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
Copolymer:
Acute Health Effects:
LD50/TDLo: Not Available
Inhalation Effects:
LC50: Not Available
*************
SECTION 6 : Emergency And First Aid Procedures
*************
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Eye Contact: Flush with plenty of water. Consult a physician if irritation persists. Skin Contact: Wash thoroughly with soap and water. Inhalation: Remove victim to fresh air. Ingestion: No hazards anticipated from swallowing small amounts incidentally to normal handling. \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* SECTION 7 : Reactivity Data \*\*\*\*\*\*\*\*\*\*\*\*\*\* Chemical Stability: Stable If No... Under What Conditions: Not Applicable. Incompatibilities with Other Materials: Incompatibility with other Substances: Yes If So... Which Ones: Avoid exposure of product to light. Reactivity: Reactivity and Under What Conditions: Avoid excessive heat and sunlight. Hazardous Polymerization: Will not occur. \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* SECTION 8 : Precautions For Safe Handling \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* Spill Cleanup Measures: Clean up mechanically. Dispose of according to local and national regulations. Storage: Store at 2-28 deg C/36-82 deg F. Waste Disposal: Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority. Transportation Information: Shipment: Not Applicable \*\*\*\*\*\*\*\*\*\*\*\*\*\*\* SECTION 9 : Control Measures \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* Ventilation System: Good general ventilation should be sufficient. Hand Protection Description: Gloves: Yes Eye/Face Protection: Safety goggles Respiratory Protection: Not required. Other Protective: Avoid direct contact with eyes and skin.

MSDS Revision Date: November 18, 2004 MSDS Author: Anderjeet Gulati Phone: (716) 691-0010

Disclaimer:

The information and recommendations are taken from sources believed to be accurate; however, Ivoclar Vivadent, Inc. makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof.



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. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 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



GHS07

- · Signal word Warning
- $\cdot \textit{Hazard-determining components of labeling:}$

urethane dimethacrylate

Bis-GMA

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

(Contd. on page 2)

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# Trade name: Tetric EvoCeram

(Contd. of page 1)

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.

#### Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

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



Health = 2Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 2Fire = 0

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

### 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	≥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.

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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)

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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

9 Physical and chemical properties					
· Information on basic physical and chemical properties · General Information					
· Appearance: Form:	Pastv				
Color:	According to product specification				
· Odor:	Characteristic				
· Odor threshold:	Not determined.				
· pH-value:	Not applicable.				
Change in condition Melting point/Melting range: Boiling point/Boiling range:	Undetermined. 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: Upper:	Not determined. Not determined.				
· Vapor pressure:	Not applicable.				
Density at 20 °C (68 °F):	2.1 g/cm³ (17.525 lbs/gal)				
Relative density	Not determined.				
Vapor density	Not applicable.				
· Evaporation rate	Not applicable.				

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Trade name: Tetric EvoCeram

(Contd. of page 4)

· Solubility in / Miscibility with

Water: Nearly insoluble.

· Partition coefficient (n-octanol/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.

(Contd. on page 6)

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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.

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- · UN-Number
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
- · UN proper shipping name
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
- · Transport hazard class(es)
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA
- · Class 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 of

MARPOL73/78 and the IBC Code 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

(Contd. on page 7)

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Trade name: Tetric EvoCeram

(Contd. of page 6)

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



GH30/

- · 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

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.

Printing date 07/22/2019 Version number 8 Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

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#### 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.

-US