SAFETY DATA SHEETS

This SDS packet was issued with item:

077126204

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 071455963 071455971 071455989 071455997
071456003 071456011 071456029 077083538 077126188 077126196 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/Vivadent
Manufacturer MSDS Number:

****
SECTION 1 : Chemical Product and Company Identification
****

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

Obtained by Global Safety Management,www.globalsafetynet.com, (877) 683-7460

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 CAS#
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

****
SECTION 3 : Physical And Chemical Characteristics

Obtained by Global Safety Management,www.globalsafetynet.com, (877) 683-7460

****

Physical State/Appearance:
 Paste
Color:
 Off white to cream colored
Odor:
 No odor
pH:
 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 g/cm3): 2.09 - 2.14 g/cm3 (20 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:
 None
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

Obtained by Global Safety Management,www.globalsafetynet.com, (877) 683-7460

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 Reg.: No
Teratogenicity:
No
Embryo Toxicity:
No
Sensitization:
No
Reproductive Toxicity:
No
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
****

Obtained by Global Safety Management,www.globalsafetynet.com, (877) 683-7460

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.

Obtained by Global Safety Management,www.globalsafetynet.com, (877) 683-7460

****
SECTION 10 : Other Information
****

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.

Obtained by Global Safety Management,www.globalsafetynet.com, (877) 683-7460

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/20/2015 *Version number 6* *Reviewed on 03/27/2015*

*

1 Identification

· **Product identifier**

· **Trade name:** **Tetric EvoCeram**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **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

· **Hazard-determining components of labeling:**
urethane dimethacrylate
Bis-GMA

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/20/2015 Version number 6 Reviewed on 03/27/2015

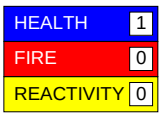
Trade name: **Tetric EvoCeram**

(Contd. of page 1)

· **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.
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
· **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 = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 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:**

72869-86-4	urethane dimethacrylate	2.5-<10%
1565-94-2	Bis-GMA	2.5-<10%
13760-80-0	ytterbium trifluoride	2.5-<10%
41637-38-1	ethyoxylated bisphenol A dimethacrylate	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.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/20/2015 Version number 6 Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(Contd. of page 2)

· **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** 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.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/20/2015 | Version number 6 | Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(Contd. of page 3)

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
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.*
· **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.
· **Eye protection:** *Safety glasses*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	*Pasty*
Color:	*According to product specification*
· **Odor:**	*Characteristic*
· **Odour 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.*

(Contd. on page 5)

Safety Data Sheet
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Trade name: **Tetric EvoCeram**

(Contd. of page 4)

· **Vapor pressure:**	Not applicable.
· **Density at 20 °C (68 °F):**	2.1 g/cm³ (17.525 lbs/gal)
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **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:**
· **Primary irritant effect:**
· **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.

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Safety Data Sheet
acc. to OSHA HCS

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Trade name: **Tetric EvoCeram**

(Contd. of page 5)

· **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.

*

14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, 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":**	-

US

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/20/2015 Version number 6 Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(Contd. of page 6)

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):**

All ingredients are listed.

· **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)**

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**

GHS07

· **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.
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

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Trade name: **Tetric EvoCeram**

(Contd. of page 7)

If eye irritation persists: Get medical advice/attention.

· ***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.*

*
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*** *04/20/2015 / 5*
· ***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)
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
· **** Data compared to the previous version altered.***