

SAFETY DATA SHEETS

This SDS packet was issued with item:

070215517

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

070386938 070386946 070386953 070386961 070386979 070386987 070386995 070387001 070387019 070387027
070442509 070442517 070442525 070442533 070442541 070442558 070442566 070442574 070442582 070442590
070442608 070442616 070442624 070442632 070442640 070442657 070442665 070442673 070442681 070442699
070442889 070442897 070442913 070442939 070442947 070442954 077143613 077143621 077143639 077143647
077143654 077144843 077173008 077173016 077173024 077173032 077173040 077173057 077173065 077173305
077173313 077173321 077173339 077173347 077173354 077173362 077173370 077173388 077173396 077173404
077173412 077173420 077173438 077173446 077173453 077173461 077173479 077173487 077173495 077173503
077173511 077173529 077173537 077173545 077173552 077173560 077173578 077173586 077173594 077173602
077173610 077173628 077173636 077173644 077173651 077173669 077173677 077173685 077173693 077173701
077173982 077173990 077174006 077174014 077174022 077174030 077174048 077174055 077174063 077174071
077174089 077174139 077174147 077174154 077174162 077174170 077174188 077174196 077174204 077174212
077174220 077174238 077174287 077174295 077174303 077174311 077174329 077174337 077174345 077174352
077174360 077174378 077174501 077174519 077174527 077174535 077174543 077174550 077174568 077174576
077174584 077174592 077174600 077174618 077174626 077174634 077174642 077174659 077174667 077174675
077174683 077174691 077174709 077174717 077174725 077174733 077174741 077174758 077174766 077174774
077174782 077174790 077174808 077174816 077174824 077174832 077174840 077174899 077175383 077176118
077176126 077176134 077176142 077176159 077176167 077176175 077176183 077176191 077176209 077176217
077176225 077176233 077176241 077176258 077176266 077176274 077176282 077176290 077176308 077176316
273010807

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).

070215368 077175359

1 Identification

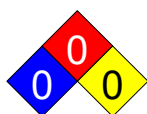
- **Product identifier**
- **Trade name:** **IPS e.max CAD**
- **CAS Number:**
66402-68-4
- **EC number:**
266-340-9
- **Application of the substance / the mixture**
Manufacture of dental prosthesis
Lithium disilicate glass-ceramic ingot for the CAD/CAM technology
- **Details of the supplier of the safety 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**
The substance is not classified according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: **IPS e.max CAD**

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)

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

- **Other hazards** Avoid breathing sanding dust /swarf.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
66402-68-4 ceramic materials
- **Identification number(s) ---**
- **EC number:** 266-340-9
- **Description:** Lithium disilicate glass-ceramic ingot

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Mechanical effects only.
- **After swallowing:**
Grinding dust: Rinse out mouth and then drink plenty of water.
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:** The product is not flammable.
- **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:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: **IPS e.max CAD**

(Contd. of page 2)

- **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:** None.
- **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:** Not required.
- **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.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:**
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Color:	According to product specification
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: **IPS e.max CAD**

(Contd. of page 3)

· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Product is not flammable.
· Auto igniting:	Not determined.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	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.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used 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 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:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

· Carcinogenic categories

· NTP (National Toxicology Program)

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

 US
 (Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: **IPS e.max CAD**

(Contd. of page 4)

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:** Generally not hazardous for water
- **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, 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 |

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: **IPS e.max CAD**

(Contd. of page 5)

15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**

Substance is not listed.

· **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

· **TSCA (Toxic Substances Control Act):**

Substance is not listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

Substance is not listed.

· **Chemicals known to cause reproductive toxicity for females:**

Substance is not listed.

· **Chemicals known to cause reproductive toxicity for males:**

Substance is not listed.

· **Chemicals known to cause developmental toxicity:**

Substance is not listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

Substance is not listed.

· **TLV (Threshold Limit Value established by ACGIH)**

Substance is not listed.

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

Substance is not listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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** 10/05/2016 / 5

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

(Contd. of page 6)

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
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

· *** Data compared to the previous version altered.**

US

Safety Data Sheet acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019



1 Identification

- **Product identifier**
- **Trade name:** ***Multilink Hybrid Abutment (Base)***
- **Application of the substance / the mixture** Self-curing dental luting composite for extraoral cementation
- **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.
Carc. 2 H351 Suspected of causing cancer.
STOT SE 3 H335 May cause respiratory irritation.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS07 GHS08
- **Signal word** Warning
- **Hazard-determining components of labeling:**
Bis-GMA
ytterbium trifluoride
titanium dioxide

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Base)**

(Contd. of page 1)

2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate

· **Hazard statements**

Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of causing cancer.
May cause respiratory irritation.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves/protective clothing/eye protection/face protection.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2
Fire = 1
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 2
Fire = 1
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:**

CAS: 13760-80-0	ytterbium trifluoride	≥20-≤25%
CAS: 36425-15-7	Bis-GMA	10-25%
CAS: 868-77-9	2-hydroxyethyl methacrylate	≥2.5-<10%
CAS: 13463-67-7	titanium dioxide	≥0.1-<2.5%
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate	≥0.1-<1%

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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Base)**

(Contd. of page 2)

- **After swallowing:**
Rinse out mouth and then drink plenty of water.
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** 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.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Base)**

(Contd. of page 3)

· **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.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

· **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.

After use of gloves apply skin-cleaning agents and skin cosmetics.

· **Material of gloves**

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

· **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: 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 applicable.

· **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 determined.

· **Density at 20 °C (68 °F):** ~1.95 g/cm³ (~16.273 lbs/gal)

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Base)**

(Contd. of page 4)

· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Nearly insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
Photoreactive (Danger of polymerization).
Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)

CAS: 13760-80-0 ytterbium trifluoride

3

· 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.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Base)**

(Contd. of page 5)

- **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/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.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Base)**

(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

CAS: 13760-80-0 ytterbium trifluoride

CAS: 1565-94-2 Bis-GMA

CAS: 868-77-9 2-hydroxyethyl methacrylate

CAS: 2867-47-2 2-dimethylaminoethyl methacrylate

CAS: 13463-67-7 titanium dioxide

ACTIVE

· **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)**

CAS: 13463-67-7 titanium dioxide

· **GHS label elements**

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

· **Hazard pictograms**

GHS07 GHS08

· **Signal word** Warning· **Hazard-determining components of labeling:**

Bis-GMA

ytterbium trifluoride

titanium dioxide

2-hydroxyethyl methacrylate

2-dimethylaminoethyl methacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Suspected of causing cancer.

May cause respiratory irritation.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

(Contd. on page 8)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/22/2019

Version number 5

Reviewed on 06/03/2019

Trade name: *Multilink Hybrid Abutment (Base)*

(Contd. of page 7)

Wear protective gloves/protective clothing/eye protection/face protection.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

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

· **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** 07/22/2019 / 4

· **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

Carc. 2: Carcinogenicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**


1 Identification

- **Product identifier**
- **Trade name:** ***Multilink Hybrid Abutment (Catalyst)***
- **Application of the substance / the mixture** Self-curing dental luting composite for extraoral cementation
- **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.
STOT SE 3 H335 May cause respiratory irritation.
- **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
ytterbium trifluoride
2-hydroxyethyl methacrylate
dibenzoyl peroxide

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Catalyst)**

(Contd. of page 1)

· Hazard statements

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

· 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.

· Classification system:

· NFPA ratings (scale 0 - 4)



Health = 2
Fire = 0
Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 2
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:

CAS: 13760-80-0	ytterbium trifluoride	20-<25%
CAS: 41637-38-1	Bis-EMA	10-<25%
CAS: 72869-86-4	urethane dimethacrylate	2.5-<10%
CAS: 868-77-9	2-hydroxyethyl methacrylate	2.5-<10%
CAS: 94-36-0	dibenzoyl peroxide	1-<2.5%

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:

Rinse out mouth and then drink plenty of water.
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 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Catalyst)**

(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)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Catalyst)**

(Contd. of page 3)

- **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.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
- **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.
After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
- **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:	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 applicable.
- **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 determined.
- **Density at 20 °C (68 °F):** ~ 1.96 g/cm³ (~16.356 lbs/gal)
- **Relative density** Not determined.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Catalyst)**

(Contd. of page 4)

- | | |
|---|--|
| · Vapor density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with Water: | Nearly insoluble. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · 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.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

CAS: 94-36-0 dibenzoyl peroxide

3

- **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.

(Contd. on page 6)

US

Safety Data Sheet acc. to OSHA HCS

Printing date 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: **Multilink Hybrid Abutment (Catalyst)**

(Contd. of page 5)

· **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 packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **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.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: Multilink Hybrid Abutment (Catalyst)

(Contd. of page 6)

· Section 313 (Specific toxic chemical listings):

CAS: 94-36-0 dibenzoyl peroxide

· TSCA (Toxic Substances Control Act):

CAS: 13760-80-0 ytterbium trifluoride

CAS: 41637-38-1 Bis-EMA

CAS: 72869-86-4 urethane dimethacrylate

CAS: 868-77-9 2-hydroxyethyl methacrylate

CAS: 94-36-0 dibenzoyl peroxide

· 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

CAS: 94-36-0 dibenzoyl peroxide

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

ytterbium trifluoride

2-hydroxyethyl methacrylate

dibenzoyl peroxide

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

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

(Contd. on page 8)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/22/2019

Version number 4

Reviewed on 06/03/2019

Trade name: Multilink Hybrid Abutment (Catalyst)

(Contd. of page 7)

*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.*

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 / 3

· **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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

US