

SAFETY DATA SHEETS

This SDS packet was issued with item:

077083538

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).

070215376 070483453 071455849 071455856 071455864 071455872 071455880 071455955 071455963 071455971
071455989 071455997 071456003 071456011 071456029 077086259 077086663 077124506 077124514 077124522
077124530 077125008 077125016 077125024 077125032 077125040 077125057 077125065 077125073 077125081
077125099 077125107 077125115 077125123 077125131 077125149 077125156 077125164 077125172 077125180
077125198 077125206 077125214 077125222 077125230 077125248 077125255 077125263 077125271 077125289
077125297 077125305 077125313 077125321 077125339 077125503 077125511 077125529 077125537 077125545
077125552 077125560 077125578 077125586 077125594 077125602 077125610 077125628 077125636 077125644
077125651 077125669 077125677 077125685 077125693 077125701 077125719 077125727 077125735 077125743
077125750 077125768 077125776 077125784 077125792 077125800 077125818 077125826 077125834 077126055
077126188 077126196 077126204 077126212 077126238 077126246 077126253 077126261 077126279 077126287
077126295 077126303 077126311 077126329 077126337 077126345 077126352 077126360 077126378 077126386
077126394 077126402 077126410 077126428 077126436 077126444 077126451 077126550 077126568 077126576
077126584 077126592 077126600 077126618 077126626 077126634 077126642 077126659 077126667 077126675
077126683 077126691 077126709 077126717 077126725 077126733 077126741 077126758 077126766 077126774
077142540 077142581 077142599 077142607 077142904 077142961 077143001 077143043 077143084 077143241
077143266 077143282 077143290 077143316 077143324 077143340 077143365 077143381 077143407 077143423

1 Identification

- **Product identifier**
- **Trade name: *IPS Empress Direct***
- **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
 - **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.

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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)**



· **HMIS-ratings (scale 0 - 4)**



· **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	10-25%
CAS: 13760-80-0	ytterbium trifluoride	≥2.5-<10%
CAS: 43048-08-4	tricyclodocane dimethanol dimethacrylate	≥2.5-<10%
CAS: 36425-15-7	Bis-GMA	≥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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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.

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- **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:	Pasty
· Color:	According to product specification
· Odor:	Characteristic
· Odor threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

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

- **Flash point:** 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):	1.94 g/cm ³ (16.189 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

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- | | |
|---|--|
| · 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.
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**
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:** 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 3 (Self-assessment): extremely hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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- **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.

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

None of the ingredients is listed.

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

All ingredients are listed.

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· **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**



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.

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.

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.

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· **Date of preparation / last revision** 03/25/2019 / 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)**HMS: 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.**

Fiche de données de sécurité
selon RPD, Annexe 1

Date d'impression : 02/05/2024

Numéro de version 9

Révision: 02/05/2024



1 Identification

- **Identificateur de produit**
- **Nom du produit:** **Monobond Plus**
- **Emploi de la substance / de la préparation** Primer universel
- **Renseignements concernant le fournisseur de la fiche de données de sécurité**
- **Producteur/fournisseur:**
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
- **Service chargé des renseignements:** Quality Assurance / Regulatory Affairs
- **Numéro d'appel d'urgence:**
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 Identification des dangers

- **Classification de la substance ou du mélange**
Liquides inflammables - catégorie 2 H225 Liquide et vapeurs très inflammables.
Irritation oculaire - catégorie 2A H319 Provoque une sévère irritation des yeux.
Sensibilisant cutané - catégorie 1 H317 Peut provoquer une allergie cutanée.
- **Éléments d'étiquetage**
- **Éléments d'étiquetage SGH** Le produit est classifié et étiqueté selon le Système Général Harmonisé (GHS).
- **Pictogrammes de danger**
 
GHS02 GHS07
- **Mention d'avertissement** Danger
- **Composants dangereux déterminants pour l'étiquetage:**
sulphide methacrylate
methacrylated phosphoric acid ester

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Nom du produit: **Monobond Plus**

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· **Mentions de danger**

Liquide et vapeurs très inflammables.
Provoque une sévère irritation des yeux.
Peut provoquer une allergie cutanée.

· **Conseils de prudence**

Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'inflammation. Ne pas fumer.
Maintenir le récipient fermé de manière étanche.
Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/aérosols.
Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
En cas d'irritation ou d'éruption cutanée: Demander un avis médical/Consulter un médecin.
Stocker dans un endroit bien ventilé. Tenir au frais.

· **Système de classification:**

· **NFPA données (gamme 0-4)**



Santé = 2
Inflammabilité = 3
Réactivité = 0

· **HMIS données (gamme 0-4)**



Santé = *2
Inflammabilité = 3
Réactivité = 0

3 Composition/information sur les ingrédients

· **Caractérisation chimique: Mélanges**

· **Description:** Mélange des substances mentionnées à la suite avec des additifs non dangereux.

· **Composants dangereux:**

CAS: 64-17-5	éthanol	80-100%p/p *
CAS: 2530-85-0	méthacrylate de 3-triméthoxysilylpropyle	1-5%p/p *
CAS: 85590-00-7	methacrylated phosphoric acid ester	0,1-1%p/p *
CAS: 1096164-11-2	sulphide methacrylate	0,1-1%p/p *

* Les plages de concentrations réelles sont conservées en tant que secret commercial.

· **Indications complémentaires:** Pour le libellé des phrases de risque citées, se référer au chapitre 16.

4 Premiers soins

· **Description des premiers secours**

· **Après inhalation:**

Donner de l'air frais, consulter un médecin en cas de troubles.
En cas d'inconscience, coucher et transporter la personne en position latérale stable.

· **Après contact avec la peau:** Laver immédiatement à l'eau.

· **Après contact avec les yeux:**

Rincer les yeux, pendant plusieurs minutes, sous l'eau courante en écartant bien les paupières et consulter un médecin.

· **Après ingestion:**

Rincer la bouche et boire beaucoup d'eau.
Si les troubles persistent, consulter un médecin.

· **Indications destinées au médecin:**

· **Principaux symptômes et effets, aigus et différés** Non disponibles.

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· **Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires** Non disponibles.

5 Mesures à prendre en cas d'incendie

- **Moyens d'extinction**
- **Moyens d'extinction:**
CO₂, poudre d'extinction ou eau pulvérisée. Combattre les foyers importants avec de l'eau pulvérisée ou de la mousse résistant à l'alcool.
- **Dangers particuliers résultant de la substance ou du mélange** Non disponibles.
- **Conseils aux pompiers**
- **Équipement spécial de sécurité:** Aucune mesure particulière n'est requise.
- **Autres indications** Refroidir les récipients en danger en pulvérisant de l'eau.

6 Mesures à prendre en cas de déversement accidentel

- **Précautions individuelles, équipement de protection et procédures d'urgence**
Porter un équipement de sécurité. Eloigner les personnes non protégées.
- **Précautions pour la protection de l'environnement:**
Ne pas rejeter dans les canalisations, dans les eaux de surface et dans les nappes d'eau souterraines.
- **Méthodes et matériel de confinement et de nettoyage:**
Recueillir les liquides à l'aide d'un produit absorbant (sable, kieselguhr, neutralisant d'acide, liant universel, sciure).
Assurer une aération suffisante.
- **Référence à d'autres rubriques**
Afin d'obtenir des informations pour une manipulation sûre, consulter le chapitre 7.
Afin d'obtenir des informations sur les équipements de protection personnels, consulter le chapitre 8.
Afin d'obtenir des informations sur l'élimination, consulter le chapitre 13.

7 Manutention et stockage

- **Manipulation:**
- **Précautions à prendre pour une manipulation sans danger**
La manipulation de ce produit doit être réservée au personnel convenablement formé.
Exclusivement réservé à l'usage dentaire.
- **Préventions des incendies et des explosions:** Aucune mesure particulière n'est requise.
- **Conditions d'un stockage sûr, y compris d'éventuelles incompatibilités**
- **Stockage:**
- **Exigences concernant les lieux et conteneurs de stockage:** Ne conserver que dans le fût d'origine.
- **Indications concernant le stockage commun:** Pas nécessaire.
- **Autres indications sur les conditions de stockage:**
Protéger de la forte chaleur et du rayonnement direct du soleil.
Tenir les emballages hermétiquement fermés.
- **Utilisation(s) finale(s) particulière(s)** Non disponibles.

8 Contrôle de l'exposition/ protection individuelle

- **Indications complémentaires pour l'agencement des installations techniques:**
Sans autre indication, voir point 7.

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Fiche de données de sécurité

selon RPD, Annexe 1

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Numéro de version 9

Révision: 02/05/2024

Nom du produit: **Monobond Plus**

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· Paramètres de contrôle	
· Composants présentant des valeurs-seuil à surveiller par poste de travail:	
CAS: 64-17-5	éthanol
EL STEL: 1000	ppm
EV TWA: 1,900	mg/m ³ , 1,000 ppm

· Informations relatives à la réglementation

EL: OHS Guidelines Part 5, Table of Exposure Limits for Chemical and Biological Substances

EV: Règl. de l'Ont. 287/17

· Remarques supplémentaires:

Le présent document s'appuie sur les listes en vigueur au moment de son élaboration.

· Contrôles de l'exposition

· **Équipement de protection individuel:**

· **Mesures générales de protection et d'hygiène:**

· Une hygiène adéquate est à respecter.

· Tenir à l'écart des produits alimentaires, des boissons et de la nourriture pour animaux.

· Se laver les mains avant les pauses et en fin de travail.

· Éviter tout contact avec les yeux et avec la peau.

· **Filtre recommandé pour une utilisation momentané:**

En cas d'exposition faible ou de courte durée, utiliser un filtre respiratoire; en cas d'exposition intense ou durable, utiliser un appareil de respiration indépendant de l'air ambiant.

· **Protection des mains:**



Gants de protection

Après l'utilisation de gants, appliquer des produits de nettoyage et de soin de la peau.

· **Matériau des gants**

Choix du matériau des gants en fonction des temps de pénétration, du taux de perméabilité et de la dégradation.

· **Temps de pénétration du matériau des gants**

Le temps de pénétration exact est à déterminer par le fabricant des gants de protection et à respecter.

· **Des gants dans les matériaux suivants ne sont pas appropriés:**

Les gants à usage médical disponibles sur le marché ne protègent pas contre les effets de sensibilisation au méthacrylate.

· **Protection des yeux:**



Lunettes de protection hermétiques

9 Propriétés physiques et chimiques

· Informations sur les propriétés physiques et chimiques essentielles

· Informations générales

· Aspect:

Forme:

Liquide

Couleur:

Incolore

· Odeur:

Genre alcool

· Seuil olfactif:

Non déterminé.

· valeur du pH:

Non déterminé.

(suite page 5)

CA/FR

Fiche de données de sécurité selon RPD, Annexe 1

Date d'impression : 02/05/2024

Numéro de version 9

Révision: 02/05/2024

Nom du produit: **Monobond Plus**

(suite de la page 4)

· Changement d'état Point de fusion/point de congélation:	-114,5 °C
Point initial d'ébullition et intervalle d'ébullition:	78 °C
· Point d'éclair	13 °C
· Température d'auto-inflammabilité:	425 °C
· Température d'inflammation:	Le produit ne s'enflamme pas spontanément.
· Propriétés explosives:	Le produit n'est pas explosif; toutefois, des mélanges explosifs vapeur-air peuvent se former.
· Limites d'explosion: Inférieure:	3,5 Vol %
Supérieure:	15 Vol %
· Pression de vapeur à 20 °C:	59 hPa
· Pression de vapeur à 50 °C:	280 hPa
· Densité à 20 °C:	0,794 g/cm ³
· Densité relative	Non déterminé.
· Densité de vapeur:	Non déterminé.
· Taux d'évaporation:	Non déterminé.
· Solubilité dans/miscibilité avec l'eau:	Soluble
· Coefficient de partage: n-octanol/eau:	Non déterminé.
· Viscosité: Dynamique:	Non déterminé.
Cinématique:	Non déterminé.
· Teneur en solvants: Solvants organiques:	96,0 %
· Teneur en substances solides:	0,0 %
· Autres informations	Non disponibles.

10 Stabilité et réactivité

- **Réactivité** Non disponibles.
- **Stabilité chimique** Stable dans les conditions normales de stockage et de manipulation.
- **Décomposition thermique/conditions à éviter:** Pas de décomposition en cas d'usage conforme.
- **Possibilité de réactions dangereuses** Aucune réaction dangereuse connue.
- **Conditions à éviter** Non disponibles.
- **Matières incompatibles:** Non disponibles.
- **Produits de décomposition dangereux:** Aucun, dans les conditions normales de stockage et d'utilisation.

11 Données toxicologiques

- **Informations sur les effets toxicologiques**
- **Toxicité aiguë**

· **Valeurs LD/LC50 déterminantes pour la classification:**

Oral	LD50	>5000 mg/kg (rat)
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CA/FR

Fiche de données de sécurité selon RPD, Annexe 1

Date d'impression : 02/05/2024

Numéro de version 9

Révision: 02/05/2024

Nom du produit: Monobond Plus

(suite de la page 5)

CAS: 64-17-5 éthanol

Oral	LD50	7060 mg/kg (rat)
Inhalatoire	LC50/4 h	20000 mg/l (rat)

- **Symptômes significatifs dans les tests sur animaux:**
- **Corrosion cutanée/irritation cutanée** Pas d'effet d'irritation.
- **Lésions oculaires graves/irritation oculaire** Pas d'effet d'irritation.
- **Sensibilisation respiratoire ou cutanée** Sensibilisation possible par contact avec la peau.
- **Indications toxicologiques complémentaires:**
L'éthanol dans les boissons alcoolisées fait partie des substances classées cancérogènes dans la liste du IARC (groupe 1). Ce produit contient de l'éthanol mais n'est pas une boisson alcoolisée consommable.
- **Catégories cancérogènes**

· IARC / CIRC (Centre International de Recherche sur le Cancer)

CAS: 64-17-5 éthanol

I

· NTP / PNT (Programme National de Toxicologie)

Aucun des composants n'est compris.

12 Données écologiques

- **Toxicité**
- **Toxicité aquatique:** Non disponibles.
- **Persistance et dégradabilité** Non disponibles.
- **Comportement dans les compartiments de l'environnement:**
- **Potentiel de bioaccumulation** Non disponibles.
- **Mobilité dans le sol** Non disponibles.
- **Autres indications écologiques:**
- **Indications générales:**
Catégorie de pollution des eaux 1 (D) (Classification propre): peu polluant
Ne pas laisser le produit, non dilué ou en grande quantité, pénétrer la nappe phréatique, les eaux ou les canalisations.
- **Résultats des évaluations PBT et VPVB**
- **PBT:** Non applicable.
- **vPvB:** Non applicable.
- **Autres effets néfastes** Non disponibles.

13 Données sur l'élimination

- **Méthodes de traitement des déchets**
- **Recommandation:**
Ne doit pas être évacué avec les ordures ménagères. Ne pas laisser pénétrer dans les égouts.
- **Emballages non nettoyés:**
- **Recommandation:** Evacuation conformément aux prescriptions légales.
- **Produit de nettoyage recommandé:** Eau, éventuellement avec des produits de nettoyage

14 Informations relatives au transport

- **Numéro ONU**
- **DOT/TMD, ADR, IMDG, IATA** UN1170

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CA/FR

Fiche de données de sécurité selon RPD, Annexe 1

Date d'impression : 02/05/2024

Numéro de version 9

Révision: 02/05/2024

Nom du produit: Monobond Plus

(suite de la page 6)

· **Désignation officielle de transport de l'ONU**
 · **DOT/TMD** ETHANOL, solution
 · **ADR** 1170 ETHANOL (ALCOOL ÉTHYLIQUE), solution
 · **IMDG** ETHANOL (ETHYL ALCOHOL) solution
 · **IATA** ETHANOL solution

· **Classe(s) de danger pour le transport**
 · **DOT/TMD (Règlement sur le transport des marchandises dangereuses):**



· **Classe** 3 Liquides inflammables.
 · **Label** 3

· **ADR**

· **Classe** 3 (F1) Liquides inflammables.
 · **Étiquette** 3

· **IMDG, IATA**

· **Class** 3 Liquides inflammables.
 · **Label** 3

· **Groupe d'emballage**· **DOT/TMD, ADR, IMDG, IATA** II· **Dangers pour l'environnement:**· **Marine Pollutant:** Non· **Précautions particulières à prendre par l'utilisateur** Attention: Liquides inflammables.· **Numéro d'identification du danger (Indice Kemler):** 33· **No EMS:** F-E,S-D· **Stowage Category** A

· **Transport en vrac conformément à l'annexe II de la convention Marpol et au recueil IBC** Non applicable.

· **Indications complémentaires de transport:**· **ADR**· **Quantités limitées (LQ)** 1L· **Quantités exceptées (EQ)** Code: E2

Quantité maximale nette par emballage intérieur: 30 ml

Quantité maximale nette par emballage extérieur: 500 ml

· **Catégorie de transport** 2· **Code de restriction en tunnels** D/E

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Fiche de données de sécurité selon RPD, Annexe 1

Date d'impression : 02/05/2024

Numéro de version 9

Révision: 02/05/2024

Nom du produit: **Monobond Plus**

(suite de la page 7)

· IMDG	1L
· Limited quantities (LQ)	Code: E2
· Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· "Règlement type" de l'ONU:	UN1170, ETHANOL (ALCOOL ÉTHYLIQUE), solution, 3, II

15 Informations sur la réglementation

· **Réglementations/législation particulières à la substance ou au mélange en matière de sécurité, de santé et d'environnement**

· **TSCA (Loi sur le contrôle des substances toxiques)**

CAS: 64-17-5	éthanol	ACTIVE
CAS: 2530-85-0	méthacrylate de 3-triméthoxysilylpropyle	ACTIVE

· **Informations de danger relatives aux produit:**

Le produit est classé et identifié suivant les directives sur les Produits dangereux

· **Éléments d'étiquetage SGH** Le produit est classifié et étiqueté selon le Système Général Harmonisé (GHS).

· **Pictogrammes de danger**



GHS02 GHS07

· **Mention d'avertissement** Danger

· **Composants dangereux déterminants pour l'étiquetage:**

sulphide methacrylate

methacrylated phosphoric acid ester

· **Mentions de danger**

Liquide et vapeurs très inflammables.

Provoque une sévère irritation des yeux.

Peut provoquer une allergie cutanée.

· **Conseils de prudence**

Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'inflammation. Ne pas fumer.

Maintenir le récipient fermé de manière étanche.

Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/aérosols.

Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.

En cas d'irritation ou d'éruption cutanée: Demander un avis médical/Consulter un médecin.

Stocker dans un endroit bien ventilé. Tenir au frais.

· **Prescriptions nationales:**

· **Autres prescriptions, restrictions et règlements d'interdiction**

Le produit est un dispositif médical conformément au règlement 2017/745 sur les dispositifs médicaux (MDR).

Ce produit est classé comme dispositif médical par rapport aux réglementations US et canadiennes et a été révisé par la "US Food and Drug Administration and Health Canada".

· **Évaluation de la sécurité chimique:** Une évaluation de la sécurité chimique n'a pas été réalisée.

CA/FR

(suite page 9)

**Fiche de données de sécurité
selon RPD, Annexe 1**

Date d'impression : 02/05/2024

Numéro de version 9

Révision: 02/05/2024

Nom du produit: Monobond Plus

(suite de la page 8)

16 Autres informations

Ces indications sont fondées sur l'état actuel de nos connaissances, mais ne constituent pas une garantie quant aux propriétés du produit et ne donnent pas lieu à un rapport juridique contractuel.

· Contact:**· Date de la plus récente version révisée de la fiche de données de sécurité 02/05/2024****· Acronymes et abréviations:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· * Données modifiées par rapport à la version précédente

CA/FR

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 01/28/2019

1 Identification


- **Product identifier**
- **Trade name:** ***Heliobond***
- **Application of the substance / the mixture** *Light-curing primer agent*
- **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:**
Bis-GMA
triethylene glycol dimethacrylate
 - **Hazard statements**
Causes skin irritation.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 01/28/2019

Trade name: **Heliobond**

(Contd. of page 1)

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 in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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 = 2
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



HEALTH 2 Health = 2
FIRE 0 Fire = 0
REACTIVITY 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: 36425-15-7	Bis-GMA	50-100%
CAS: 109-16-0	triethylene glycol dimethacrylate	25-50%

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:** Immediately 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.

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Reviewed on 01/28/2019

Trade name: **Heliobond**

(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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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.
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.

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Trade name: **Heliobond**

(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.
 Do not inhale gases / fumes / aerosols.
 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.*
- **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:	Fluid
Color:	Yellowish
Odor:	Characteristic
Odor threshold:	Not determined.

· **pH-value:** Not determined.

· 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.

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Reviewed on 01/28/2019

Trade name: **Heliobond**

(Contd. of page 4)

· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	1.14 g/cm ³ (9.513 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

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**
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:** Irritant to skin and mucous membranes.
 - **on the eye:** Irritating effect.
 - **Sensitization:** Sensitization possible through skin contact.
 - **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
 - **Carcinogenic categories**
- | |
|--|
| · NTP (National Toxicology Program) |
| None of the ingredients is listed. |
| · OSHA-Ca (Occupational Safety & Health Administration) |
| None of the ingredients is listed. |

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Safety Data Sheet acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 01/28/2019

Trade name: **Heliobond**

(Contd. of page 5)

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 2 (Self-assessment): hazardous for water
Do not allow product 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 |

US
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Trade name: **Heliobond**

(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)

None of the ingredients is listed.

· 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:

Bis-GMA

triethylene glycol dimethacrylate

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

Continue rinsing.

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Safety Data Sheet acc. to OSHA HCS

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Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 7)

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.*

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** 03/25/2019 / 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)

HMS: 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

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
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- Ivoclar Vivadent Inc.
1-6600 Dixie Road
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- **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
 - **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.

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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)**



· **HMIS-ratings (scale 0 - 4)**



· **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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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.

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- **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:	Pasty
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

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

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapor pressure:** Not applicable.

Density at 20 °C (68 °F):	2.1 g/cm ³ (17.525 lbs/gal)
Relative density	Not determined.
Vapor density	Not applicable.
Evaporation rate	Not applicable.

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- | | |
|---|--|
| · 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.

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- **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.

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

None of the ingredients is listed.

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

CAS: 72869-86-4 urethane dimethacrylate

CAS: 1565-94-2 Bis-GMA

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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**



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.

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.

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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.**