ivoclar

Safety Data Sheet
according to HPR, Schedule 1

Printing date 10/10/2023 *Version number 2* *Reviewed on 07/18/2023*

1 Identification

· **Product identifier**

· **Trade name: Telio Inlay**

· **Application of the substance / the mixture** Light-curing temporary 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

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2 Hazard identification

· **Classification of the substance or mixture**
Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.
Reproductive Toxicity - Category 1B H360 May damage fertility or the unborn child.

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**
Hexanedioic acid, polymer with 2,2'-oxybis[ethano1], 1,6-diisocyanato-2,2,4(or 2,4,4)-trimethylhexane, 2-hydroxyethyl methacrylate-blocked
ethyl p-dimethylaminobenzoate
1,10-decandiol dimethacrylate
dipotassium hexafluorotitanate
· **Hazard statements**
May cause an allergic skin reaction.

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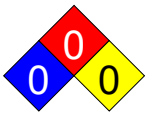
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May damage fertility or the unborn child.

· **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
If skin irritation or rash occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

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3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 2792159-54-5	Hexanedioic acid, polymer with 2,2'-oxybis[ethano1], 1,6-diisocyanato-2,2,4(or 2,4,4)-trimethylhexane, 2-hydroxyethyl methacrylate-blocked	15-40% w/w *
CAS: 6701-13-9	1,10-decandiol dimethacrylate	0.1-1% w/w *
CAS: 16919-27-0	dipotassium hexafluorotitanate	0.1-1% w/w *
CAS: 10287-53-3	ethyl p-dimethylaminobenzoate	0.1-1% w/w *

* Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:**
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.

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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**
Wear protective equipment. Keep unprotected persons away.
· **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.

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8 Exposure controls/ Personal protection

· **Additional information about design of technical systems:** No further data; see section 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
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.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.

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Avoid contact with the skin.
· **Breathing equipment:** Not required.
· **Protection of hands:**



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.
· **Material of gloves**
Butyl rubber, BR
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Goggles recommended during refilling.

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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.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not determined.
· **Density at 20 °C:**	1.358 - 1.392 g/cm³
· **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.

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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** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** None under normal conditions of storage and use.

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11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Specific symptoms in biological assay:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

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12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

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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/TDG, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT/TDG, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT/TDG, ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II 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

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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.

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



GHS07 GHS08

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· **Signal word** Danger

· **Hazard-determining components of labeling:**
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ethyl p-dimethylaminobenzoate
1,10-decandiol dimethacrylate
dipotassium hexafluorotitanate

· **Hazard statements**
May cause an allergic skin reaction.
May damage fertility or the unborn child.

· **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
If skin irritation or rash occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.

· **National regulations:**

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

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

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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.

· **Contact:**

· **Date of the latest revision of the safety data sheet** 10/10/2023

· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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