

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

1 Identification

- · Product identifier
- · Trade name: Telio CS Desensitizer
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Desensitizer
- · 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 Dam. 1 H318 Causes serious eye damage.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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







GHS05

GHS07

· Signal word Danger

· Hazard-determining components of labeling: glutaral

(Contd. on page 2)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

(Contd. of page 1)

polyethylene glycol dimethacrylate

· Hazard statements

Causes skin irritation.

Causes serious eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

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

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

Wash contaminated clothing before reuse.

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

If eye irritation persists: Get medical advice/attention.

· Additional information:

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

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



Health = 2 Fire = 0Reactivity = 0

· 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:		
25852-47-5	polyethylene glycol dimethacrylate	25-50%
111-30-8	glutaral	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: Immediately rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Do not induce vomiting; immediately call for medical help.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

(Contd. on page 3)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

(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.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.
- · Additional information Cool endangered receptacles with water spray.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

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).

Dispose contaminated material as waste according to item 13.

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: 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.

(Contd. on page 4)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

(Contd. of page 3)

· Control parameters

· Components with limit values that require monitoring at the workplace:

111-30-8 glutaral

REL Ceiling limit value: 0.8 mg/m³, 0.2 ppm

See Pocket Guide App. C

TLV Ceiling limit value: 0.2 mg/m³, 0.05 ppm

(SEN) NIC-DSEN; RSEN; activated or inactivated

- · 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.

Immediately remove all soiled and contaminated clothing.

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:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

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

Form: Fluid

(Contd. on page 5)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

		(Contd. of page
Color:	Colorless	
· Odor:	Characteristic	
· Odour 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.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not determined.	
Density at 20 °C (68 °F):	1.067 g/cm³ (8.904 lbs/gal)	
Relative density	Not determined.	
· Vapour density	Not determined.	
Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Fully miscible.	
Partition coefficient (n-octanol/wate	r): 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 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

- $\cdot \textbf{Information on toxicological effects}$
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

<i>111-30-8</i>	glutaral
-----------------	----------

Oral	LD50	134 mg/kg (rat)
Dermal	LD50	2560 mg/kg (rabbit,

(Contd. on page 6)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

(Contd. of page 5)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: Strong irritant with the danger of severe eye injury.
- · Sensitization:

Sensitization possible through inhalation.

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 product to reach ground water, water course or sewage system, even in small quantities.

- · 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 Trans	port inj	tormai	tion
----------	----------	--------	------

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

(Contd. on page 7)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

	(Contd. of page
· Packing group · DOT, ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	-

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)

111-30-8 glutaral

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).

(Contd. on page 8)

Printing date 05/19/2015 Version number 3 Reviewed on 04/09/2015

Trade name: Telio CS Desensitizer

(Contd. of page 7)

· Hazard pictograms







· Signal word Danger

· Hazard-determining components of labeling:

glutaral

polyethylene glycol dimethacrylate

· Hazard statements

Causes skin irritation.

Causes serious eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

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

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

Wash contaminated clothing before reuse.

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

If eye irritation persists: Get medical advice/attention.

· 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 05/19/2015 / 2

· 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* * Data compared to the previous version altered.