

SAFETY DATA SHEET (GHS)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER**1.1 Product identifier:-**

Product name: Telio CS Desensitizer
Product number: Void

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses: Desensitizer

1.4 Details of the manufacturer and importer:-

Manufacturer: Ivoclar Vivadent AG
 Bendererstrasse 2
 FL-9494 Schaan
 PRINCIPALITY OF LIECHTENSTEIN

Importer: Ivoclar Vivadent Pty Ltd
 1- 5 Overseas Drive Noble Park North VIC 3174
 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645
 Email: info@ivoclarvivadent.com

1.5 Emergency phone number: 13 11 26
 Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION**2.1 GHS Classification:-**

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.

2.2 GHS Label elements, including precautionary statements:-**Hazard Pictogram:**

GHS05



GHS07



GHS08

Signal word:**Hazard-determining components of labelling:****Hazard statements:**

Danger
 glutaral
 polyethylene glycol dimethacrylate
 H315 Causes skin irritation.
 H318 Causes serious eye damage.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 H317 May cause an allergic skin reaction.
 H335 May cause respiratory irritation.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P363 Wash contaminated clothing before reuse.

Precautionary statements:

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

- 2.3 Additional information:** Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other hazards:-

Results of PBT and vPvB assessment;

Void

PBT:

Not applicable.

vPvB:

Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

Ingredient name	CAS No.	Classification	Concentration
polyethylene glycol dimethacrylate	25852-47-5	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	25-50%
glutaral	111-30-8	Acute Tox. 3, H301; Acute Tox. 3, H331; Resp. Sens. 1, H334; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Skin Sens. 1, H317	3-<10%

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

If inhaled:

Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

In case of skin contact:

Immediately rinse with water

In case of eye contact:

Rinse opened eye for several minutes under running water.
Then consult a doctor

If swallowed:

Do not induce vomiting; call for medical help immediately.

4.2 Symptoms caused by exposure:-

No further relevant information available

4.3 Medical attention and special treatment:-

No further relevant information available.

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam

Unsuitable extinguishing media:

Water with full jet

5.2 Specific hazards arising from the substance/mixture/product:-

No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment:

Mouth respiratory protective device.

Precautions:

Cool endangered receptacles with water spray.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:-

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and materials 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
 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

7.1 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.

7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle
 Keep container tightly sealed.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

Component	CAS No.	Value	Parameters	Basis
glutaral	111-30-8	Short-term value: 0.2 mg/m ³ , 0.05 ppm Long-term value: 0.2 mg/m ³ , 0.05 ppm Sen		

Ingredients with biological limit values:

8.2 Biological monitoring:-

The lists valid during the making 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.

8.3 Control banding:-

Void

8.4 Engineering controls:-

Void

8.5 Individual protection measures include PPE:-

Eye/face protection:



Skin protection:

Safety glasses

Tightly sealed goggles Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

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


Respiratory protection:


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.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

9. PHYSICAL/CHEMICAL PROPERTIES
9.1 Information on physical/chemical properties:-

a)	Appearance/Form:	Fluid
b)	Colour:	Colourless
c)	Odour:	Characteristic
d)	Odour threshold:	Not determined.
e)	pH-value (10 g/l) at 20 °C:	Not determined.
f)	Melting point/melting range:	Not determined.
g)	Boiling point/boiling range:	Not determined.
h)	Flash point:	Not determined.
i)	Ignition temperature:	Not determined.
j)	Self-igniting:	Product is not self-igniting.
k)	Danger of explosion:	Not determined.
l)	Upper/lower flammability or explosive limits:	Lower Not determined Upper Not determined.
m)	Vapour pressure 20°C:	Not determined.
n)	Density at 20°C:	1.067 g/cm ³
o)	Relative density:	Not determined.
p)	Vapour density:	Not applicable.
q)	Evaporation rate:	Not applicable.
r)	Solubility in/miscibility with water:	Fully miscible.
s)	Partition coefficient: n- octanol/water:	Not determined.
t)	Viscosity:	Dynamic Not applicable. Kinematic Not applicable.
u)	Solids content:	Not determined.

10. STABILITY AND REACTIVITY
10.1 Reactivity:-

No further relevant information available.

10.2 Chemical stability:-

Stable under normal handling and storage conditions.

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications

10.3 Possibility of hazardous reactions:-

No further relevant information available.

10.4 Conditions to avoid:-

Keep away from heat and direct sunlight

10.5 Incompatible materials:-

No further relevant information available.

10.6 Hazardous decomposition products:-

None under normal conditions of storage and use.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

LD/LC50 values relevant for classification:

111-30-8 glutaral

Oral LD50 134 mg/kg (rat)

Dermal LD50 2560 mg/kg (rabbit)

Skin corrosion/irritation:

Serious eye damage/eye irritation:

Respiratory or skin sensitization:

Germ cell mutagenicity:

Carcinogenicity:

Reproductive toxicity:

Specific target organ toxicity - single exposure:

Specific target organ toxicity - repeated exposure:

Aspiration hazard:

Additional information:

Irritant to skin and mucous membranes

Strong irritant with the danger of severe eye injury

Sensitisation possible through inhalation.

Sensitisation possible through skin contact

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

Long Term (Chronic) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

11.3 Early onset symptoms related to exposure:-

11.4 Delayed health effects from exposure:-

11.5 Exposure levels and health effects:-

11.6 Interactive effects:-

11.7 Other:-

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

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No further relevant information available.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

No further relevant information available.

12.2 Persistence/degradability:-

No further relevant information available.

12.3 Bioaccumulative potential:-

No further relevant information available.

12.4 Mobility in soil:-

No further relevant information available.

12.5 Other adverse effects:-

No further relevant information available.

Additional ecological information / General notes:-

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

Uncleaned packaging:

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

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:-

Void.

UN proper shipping name or technical name:-

ADR:

Void.

IMDG, IATA:

Void.

Transport hazard class(es):

Void.

Label:

Void.

Packaging group:

Void.

Environmental hazards:

Not applicable.

Special precautions for user:

Not applicable.

Danger code:

Void.

EMS Number:

Void.

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).

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

The product is a medical device according to the Directive 93/42/EEC.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-

H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.

Key literature references/data sources used to compile SDS:-

Void

Copyright statement:-

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.

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.

IATA: International Air Transport Association.

GHS: Globally Harmonised System of Classification and Labelling of Chemicals.

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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

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

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

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

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Users should rely on their own knowledge and inquiries and make their own determination as to the applicability of this information in relation to their particular purposes and specific circumstances. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace and in conjunction with other substances or products.

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