SAFETY DATA SHEET (GHS)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-

Product name: **SR Vivodent PE / SR Orthosit PE / SR Orthotyp PE**

1.2 Other means of identification:-

Not applicable.

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

Not applicable.

Identified uses: Manufacture of dental prosthesis/ Resin teeth.

1.4 Details of the manufacturer and importer:-

Manufacturer:
Ivoclar Vivadent AG
Bendererstrasse 2 FL-9494 Schaan
Principality of Liechtenstein
Tel: + 423 235 35 35 Fax: + 423 235 33 60

Importer:
Ivoclar Vivadent Ltd
12 Omega St, Rosedale, Auckland, New Zealand
Phone +64 9 914 9999 Fax +64 9 914 9990
www.ivoclarvivadent.co.nz

1.5 Emergency phone number:
0800 764 766 (National Poison Centre)
Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

Void.

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram: Void.
Signal word: Void.
Hazard statements: Void.
Precautionary statements: Void.
Additional information:
Avoid breathing sanding dust/ swarf.

2.3 Other hazards:-

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient name	CAS No.	Classification	Concentration
Void.			
Non-hazardous ingredients	N/A	N/A	to 100%

Resin teeth based on polymethylmethacrylate
For the full text of the H-Statements mentioned in this Section, refer to Section 16.

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

General advice:
No special measures required.
Remove contaminated clothing and shoes immediately and launder thoroughly before reusing.
First aid facilities include first aid rooms and medical centres.
If a risk assessment determines that a first aid room or medical centre is not needed, a rest area within the

		workplace may be suitable to assist an injured or ill person.
	If inhaled:	Remove affected person from the immediate area. Ensure supply of fresh air and consult a doctor in case of complaints. Keep patient warm. In case of unconsciousness place patient stably in side position for transportation.
	In case of skin contact:	Wash off immediately with water. Generally the product does not irritate the skin. If skin irritation occurs, consult a doctor.
	In case of eye contact:	Mechanical effects only. Remove contact lenses, irrigate copiously with clean, fresh water for at least 15 minutes holding the eyelids apart and consult a doctor.
	If swallowed	Do not induce vomiting. Rinse mouth thoroughly with water. Let plenty of water be drunk in small gulps. Never give anything by mouth to an unconscious person. Seek medical treatment immediately**.**
4.2	**Symptoms caused by exposure:-**	Please refer to section 2.2 and section 11.
4.3	**Medical attention and special treatment:-**	No further relevant information available.

5. FIRE FIGHTING MEASURES

5.1	**Suitable extinguishing equipment:-**	
	Suitable extinguishing media:	Carbon dioxide, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
	Unsuitable extinguishing media:	Water 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:	Wear self-contained respiratory protective device.
	Precautions:	Cool endangered receptacles with water spray.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

No special measures required.
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation.
Use of suitable equipment (incl PPE) to prevent contamination of skin, eyes, clothing, removal of ignition sources, ventilation, emergency procedures (eg. evacuate, consult expert).

6.2 Environmental precautions:-

No special measures required.

6.3 Methods and materials for containment and cleaning up:-

Pick up mechanically.
Dispose contaminated material as waste according to item 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling:-

No special measures necessary if stored and handled as prescribed.
Only adequately trained personnel should handle this product.
Ensure good ventilation/exhaustion at the workplace.
Wash hands before breaks and after work.
Do not eat, drink or smoke during work time.
Remove soiled or soaked clothing immediately.
Keep away from foodstuffs and beverages.

7.2 Conditions for safe storage, including any incompatibilities:-
Keep only in the original container.
Keep container tightly sealed.
Store in cool, dry conditions in well-sealed receptacles.
Store receptacle in a well ventilated area.
Recommended storage temperature for storage rooms and vessels is 20 - 30°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-
Occupational exposure limits:
Ingredients with biological values:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Ingredients with biological limit values:
Exposure should be kept to as low as practicable and below the AOES.

8.2 Biological monitoring:-
Assess in accordance with exposure limits – please refer to section 8.1.
Exposure controls / Personal protective equipment / General protective and hygienic measures:
Usual hygienic measures for dental practice.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Use respiratory protective device against the effects of fumes/dust/aerosol.
Avoid contact with the eyes and skin.
Always wear safety goggles during mechanical processing (grinding/sawing/cutting/drilling/milling).

8.3 Control banding:-
Use good industrial hygiene practice and general ventilation**.**

8.4 Engineering controls:-
In case of intensive contact, wear protective gloves (EN 374).
Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).
Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.
Protective gloves shall be replaced immediately when physically damaged or worn.

8.5 Individual protection measures include PPE:-

Eye/face protection:

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

Skin protection:

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 Butyl rubber, BR. Fluorocarbon rubber (Viton). PVA 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 cannot 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.
Respiratory protection:	Provide for good ventilation of working area (local exhaust ventilation, if necessary). 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:-**	Solid.
b)	**Colour:-**	According to product specification.
c)	**Odour:**	Odourless.
d)	**Odour threshold:**	Not determined.
e)	**pH value:**	Not applicable.
f)	**Melting point/melting range:**	Undetermined.
g)	**Boiling point/boiling range:**	Undetermined.
h)	**Flash point:**	Not applicable.
i)	**Ignition temperature:**	Not determined.
j)	**Self-igniting:**	Product is not self-igniting.
k)	**Danger of explosion:**	Product does not present an explosion hazard.
l)	**Upper/lower flammability or explosive limits:**	Lower: Not determined. Upper: Not determined.
m)	**Vapour pressure:**	Not applicable.
n)	**Density at 20°C:**	Not determined.
o)	**Relative density:**	Not determined.
p)	**Vapour density:**	Not applicable.
q)	**Evaporation rate:**	Not applicable.
r)	**Solubility in/miscibility with water:**	Insoluble.
s)	**Partition coefficient: n- octanol/water:**	Not determined.
t)	**Viscosity:**	Dynamic: Not applicable. Kinematic: Not applicable.
u)	**Solids content:**	100%

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 dangerous reactions known.
10.4 Conditions to avoid:-
No further relevant information available.
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:
No further relevant information available.

Skin corrosion/irritation:	No irritant effect.
Serious eye damage/eye irritation:	No irritating effect.
Respiratory or skin sensitization:	No sensitising effects known.
Additional toxicology information:	No further relevant information available.
Germ cell mutagenicity:	No further relevant information available.
Carcinogenicity:	No further relevant information available.
Reproductive toxicity:	No further relevant information available.
Specific target organ toxicity - single exposure:	No further relevant information available.
Specific target organ toxicity - repeated exposure:	No further relevant information available.
Aspiration hazard:	No further relevant information available.
Additional information:	No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:	No further relevant information available.
Swallowed:	No further relevant information available.
Eyes:	No further relevant information available.
Skin:	No further relevant information available.
Inhaled:	No further relevant information available.
Long Term (Chronic) Exposure:	No further relevant information available.
Swallowed:	No further relevant information available.
Eyes:	No further relevant information available.
Skin:	No further relevant information available.
Inhaled:	No further relevant information available.
11.3 Early onset symptoms related to exposure:-	No further relevant information available.
11.4 Delayed health effects from exposure:-	No further relevant information available.
11.5 Exposure levels and health effects:-	No further relevant information available.
11.6 Interactive effects:-	No further relevant information available.
11.7 Other:-	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:

Generally not hazardous for water.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

Must not be disposed together with household garbage.
Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal.
Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.
Disposal must be made according to official regulations.
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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:	No.
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.
Additional information – ADR:-	Product is not classified as a dangerous good for transport.

15. REGULATORY INFORMATION

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

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.
Standard for the Uniform Scheduling of Medicines and Poisons.
Carcinogen classification under WHS Regulation 2011, Schedule 10.
Notification status in accordance with section 3 and current national legislation.
HSNO Approval: N/A
EPA NZ Classes of hazardous properties: N/A

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-	Void.

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

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).
Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).
Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

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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).
Aquatic Acute 1: Hazardous to the aquatic environment – AcuteHazard, Category 1.
Aquatic Chronic 1: Hazardous to the aquatic environment – Chronic Hazard, Category 1.
Aquatic Chronic 3: Hazardous to the aquatic environment – Chronic Hazard, Category 1.
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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