

SAFETY DATA SHEET (GHS)

30.11.2018
1.0.0
29.11.2023
30.11.2018

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

1.1	I.1 Product identifier:-		
	Product name:	IPS d.SIGN Margin Build-Up Liquid	
	Product number:	556648	
1.2	Other means of identification:-	I	
	Not applicable.		
1.3			
	Identified uses:	Manufacture of dental prosthesis	
1.4	Details of the manufacturer and importer:	•	
1.7	Manufacturer:	Ivoclar Vivadent AG	
	Wallulacturel.	Bendererstrasse 2	
		FL-9494 Schaan	
		PRINCIPALITY OF LIECHTENSTEIN	
		Tel: +423 235 35 35	
		Fax: +423 235 33 60	
	Importer:	Ivoclar Vivadent Ltd	
	importer.	12 Omega St, Rosedale, Auckland, New Zealand	
		Phone +64 9 914 9999 Fax +64 9 914 9990	
		www.ivoclarvivadent.co.nz	
4 E			
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:-		nary statements'-	
	Hazard Pictogram:	Void	
	Signal word:	Void	
	Hazard-determining components of	Void	
	labelling:		
	Hazard statements:	Dust generation	
		Particular danger of slipping on leaked/spilled product	
	Precautionary statements:	Void	

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;

PBT:Not applicable.**vPvB:**Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

For the full text of the H-Statements mentioned in this Section, refer to Section 16.



FIRST AID MEASURES 4.

4.1 Description of necessary first aid measures:-

	If inhaled:	Supply fresh air; consult doctor in case of complaints. In case of unconsciousness place patient stably in side position for transportation.
	In case of skin contact:	Rinse with water.
		Generally the product does not irritate the skin.
	In case of eye contact:	Rinse opened eye for several minutes under running
		water. If symptoms persist, consult a doctor.
		Mechanical effects only.
	If swallowed:	Rinse out mouth and then drink plenty of water.
		If symptoms persist consult doctor.
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:	The product is not flammable.
	Unsuitable extinguishing media:	No further relevant information available.
5.2	Specific hazards arising from the	No further relevant information available.

- 5.2 Specific hazards arising from the substance/mixture/product:-
- 5.3 Special protective equipment and precautions for fire fighters:-Special personal protective equipment: No further relevant information available Precautions: No further relevant information available

6. ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures:-Particular danger of slipping on leaked/spilled product
- 6.2 **Environmental precautions:-**Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and materials for containment and cleaning up:-Pick up mechanically. 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.

HANDLING AND STORAGE 7.

7.1 Precautions for safe handling:-

Only adequately trained personnel should handle this product. Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace

7.2 Conditions for safe storage, including any incompatibilities:-Store only in the original receptacle. Keep container tightly sealed. Store in dry conditions.

EXPOSURE CONTROLS/PERSONAL PROTECTION 8.

8.1 **Exposure control measures:-**

Occupational	exposure limits:	

Component	CAS No.	Value	Parameters	Basis
zirconium dioxide	1314-23-4	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr		



Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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. Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Vacuum clean contaminated clothing. Do not blow or brush off contamination. Do not inhale dust / smoke / mist.

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

- 8.4 Engineering controls:-
 - Void
- 8.5 Individual protection measures include PPE:-Eye/face protection:



Skin protection:

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

Protection of hands: Not Required



Respiratory protection:



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.

Recommended filter device for short term use: Filter P2

- 9. PHYSICAL/CHEMICAL PROPERTIES
- 9.1 Information on physical/chemical properties:-
- Appearance/Form: Fluid a) Colour: Colourless b) Odour: Odourless c) Odour threshold: d) Not determined. e) pH value: Not applicable. Not applicable. f) Melting point/melting range: Boiling point/boiling range: 100℃ g) Flash point: Not applicable. h) Ignition temperature: Not applicable. i) Self-igniting: Product is not self-igniting. j) Danger of explosion: Not determined. k) Upper/lower flammability or explosive Lower Not determined. I) limits: Upper Not determined.



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m)	Vapour pressure:	23 hPa		
n)	Density at 20°C:	Not applicable.		
o)	Relative density:	Not determined.		
p)	Vapour density:	1 g/cm³		
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:	Not determined.		
10.	STABILITY AND REACTIVITY			
10.1	Reactivity:-			
10.1	No further relevant information available.			
10.2	Chemical stability:-			
	Stable under normal handling and storage cor	nditions.		
	Thermal decomposition / conditions to be a			
	No decomposition if used according to specific			
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:	Mechanical effects only.		
	Respiratory or skin sensitization:	No sensitizing effects known.		
	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	No further relevant information available.		
	exposure:			
	Specific target organ toxicity - repeated	No further relevant information available.		
	exposure:			
	Aspiration hazard: Additional information:	No further relevant information available.		
	Additional information:	No further relevant information available		
11.2	Information on possible routes of exposure	a'-		
	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	No further relevant information available.		



exposure:-

- 11.4 Delayed health effects from exposure:-
- 11.5 Exposure levels and health effects:-
- 11.6 Interactive effects:-
- 11.7 Other:-
- 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:-Do not allow undiluted product o

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

Additional ecological information / General notes:-

No further relevant information available.

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. Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:-	Void.
UN proper shipping name or technical nam	e:-
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	Not applicable.
MARPOL73/78 and the IBC Code:	
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:-

Void

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. Lig. 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. **Disclaimer:-**Ivoclar Vivadent Ltd believes the information in this document to be accurate as at the date of preparation, but, to the maximum extent permitted by law, lvoclar Vivadent Ltd accepts no responsibility for any loss or damage caused by any person acting or refraining from action because of this information. The provision of this information should not be construed by anyone as a recommendation to use this product. In particular, no one should use any product in violation of any patent or other intellectual

proprietary rights or in breach of any statute or regulation.

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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