

Printing date 13.05.2024 Version number 7 (replaces version 6) Revision: 13.05.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- · Trade name: IPS Margin Sealer
- $\cdot \textit{1.2 Relevant identified uses of the substance or \textit{mixture and uses advised against}}$

No further relevant information available.

- Application of the substance / the mixture Auxiliary for manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 Fax: +423 235 33 60

· Further information obtainable from:

Regulatory Affairs sds@ivoclar.com

· 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Repr. 2 H361f Suspected of damaging fertility.
STOT SE 3 H336 May cause drowsiness or dizziness.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways. Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- · 2 2 I ahel elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

· Hazard pictograms









GHS02 GF

GHS07

GHS08

GHSO

- · Signal word Danger
- · Hazard-determining components of labelling: n-hexane
- · Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

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H336 May cause drowsiness or dizziness.

H373 May cause damage to organs through prolonged or repeated exposure.

H304 May be fatal if swallowed and enters airways.

(Contd. on page 2)

Printing date 13.05.2024 Version number 7 (replaces version 6) Revision: 13.05.2024

Trade name: IPS Margin Sealer

(Contd. of page 1)

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P331 Do NOT induce vomiting.

P405 Store locked up.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

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

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 110-54-3	n-hexane	50-100%
EINECS: 203-777-6	Flam. Liq. 2, H225; Repr. 2, H361f; STOT RE 2, H373; Asp.	
Reg.nr.: 01-2119474209-33-XXXX	Tox. 1, H304; Aquatic Chronic 2, H411; Skin Irrit. 2, H315;	
	STOT SE 3, H336	
	Specific concentration limit: STOT RE 2; H373: C ≥ 5 %	
41114 1 C 4 F 4	1: 6.1 1: (11 1 1 1 1 6 4 4 6 4 4 6 4 6 4 6 4 6 6 6 6	

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
- · After inhalation:

Supply fresh air.

Seek medical treatment.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Do not induce vomiting; call for medical help immediately.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray.
- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- Protective equipment: Wear self-contained respiratory protective device.
- · Additional information Cool endangered receptacles with water spray.

GB

Printing date 13.05.2024

Version number 7 (replaces version 6)

Trade name: IPS Margin Sealer

(Contd. of page 2)

Revision: 13.05.2024

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.

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

· 6.3 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 section 13.

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

· 6.4 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.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Only adequately trained personnel should handle this product.

For use in dentistry only.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store in a cool location.

Store only in the original receptacle.

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store receptacle in a well ventilated area.

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

CAS: 110-54-3 n-hexane

WEL Long-term value: 72 mg/m³, 20 ppm

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

(Contd. on page 4)

Printing date 13.05.2024

Version number 7 (replaces version 6)

Trade name: IPS Margin Sealer

(Contd. of page 3)

Revision: 13.05.2024

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not inhale gases / fumes / aerosols.

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 A1

Filter A2

Filter A3

· Hand protection



Protective gloves (EN 374)

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

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Nitrile rubber, NBR

Fluorocarbon rubber (Viton)

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.

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/face protection



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

Fluid · Physical state · Colour: Colourless · Odour: Characteristic Odour threshold: Not determined. -95 °C

· Melting point/freezing point: · Boiling point or initial boiling point and boiling

69°C · Flammability Highly flammable.

· Lower and upper explosion limit

1.2 Vol % · Lower: 7.4 Vol % · Upper:

(Contd. on page 5)

Printing date 13.05.2024 Version number 7 (replaces version 6) Revision: 13.05.2024

Trade name: IPS Margin Sealer

(Contd. of page 4)

· Flash point:	-26 °C
· Auto-ignition temperature:	240 °C

• Decomposition temperature: Not determined. • pH Not determined.

· Viscosity:

Kinematic viscosityDynamic:Not determined.Not determined.

Solubility

• water at 20 °C: 0.1 g/l

• Partition coefficient n-octanol/water (log value) Not determined. • Vapour pressure at 20 °C: 160 hPa

Density and/or relative density

Density at 20 °C: 0.65 g/cm³
 Relative density Not determined.
 Vapour density Not determined.

· 9.2 Other information

· Appearance:

· Form: Fluid

Important information on protection of health and

environment, and on safety.

• **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product is not explosive. However, formation of

explosive air/vapour mixtures are possible.

· Solvent content:

· Organic solvents: 96.0 %
· Solids content: 0.0 %

· Change in condition

• Evaporation rate Not determined.

· Information with regard to physical hazard classes

Explosives Void
Flammable gases Void
Aerosols Void
Oxidising gases Void
Gases under pressure Void

• Flammable liquids Highly flammable liquid and vapour.

· Flammable solids Void
· Self-reactive substances and mixtures Void
· Pyrophoric liquids Void
· Pyrophoric solids Void
· Self-heating substances and mixtures Void
· Substances and mixtures, which emit flammable
gases in contact with water Void

gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void
Organic peroxides Void
Corrosive to metals Void
Desensitised explosives Void

SECTION 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.

(Contd. on page 6)

Printing date 13.05.2024 Version number 7 (replaces version 6) Revision: 13.05.2024

Trade name: IPS Margin Sealer

(Contd. of page 5)

- 10.3 Possibility of hazardous reactions Reacts with strong oxidising agents.
- · 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.

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50	values	relevant	for	classi	fication:
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CAS: 110-54-3 n-hexane

 Oral
 LD50
 28710 mg/kg (rat)

 Dermal
 LD50
 >2000 mg/kg (rabbit)

- · Skin corrosion/irritation Causes skin irritation.
- · Reproductive toxicity Suspected of damaging fertility.
- · STOT-single exposure May cause drowsiness or dizziness.
- · STOT-repeated exposure May cause damage to organs through prolonged or repeated exposure.
- · Aspiration hazard May be fatal if swallowed and enters airways.
- · Additional toxicological information: No further relevant information available.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and 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 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Also poisonous for fish and plankton in water bodies.

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

Toxic for aquatic organisms

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

(Contd. on page 7)

Version number 7 (replaces version 6) Printing date 13.05.2024 Revision: 13.05.2024

Trade name: IPS Margin Sealer

(Contd. of page 6)

- · Uncleaned packaging:
 · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information		
· 14.1 UN number or ID number · ADR/RID/ADN, IMDG, IATA	UN1208	
· 14.2 UN proper shipping name · ADR/RID/ADN · IMDG · IATA	1208 HEXANES HEXANES, MARINE POLLUTANT HEXANES	
· 14.3 Transport hazard class(es)		
· ADR/RID/ADN		
1 1 1 1 1 1 1 1 1 1		
· Class	3 (F1) Flammable liquids.	
· Label	3	
· IMDG		
· Class · Label	3 Flammable liquids. 3	
	<u> </u>	
· Class · Label	3 Flammable liquids.	
· 14.4 Packing group · ADR/RID/ADN, IMDG, IATA	II	
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances: n-hexane	
· Marine pollutant:	Yes	
	Symbol (fish and tree)	
· Special marking (ADR/RID/ADN):	Symbol (fish and tree)	
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-D E	
· 14.7 Maritime transport in bulk according to IM		
instruments	Not applicable.	
	(Contd. on page	

Printing date 13.05.2024 Version number 7 (replaces version 6) Revision: 13.05.2024

Trade name: IPS Margin Sealer

	(Contd. of page
Transport/Additional information:	
ADR/RID/ADN	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN1208, HEXANES, ENVIRONMENTALLY
5	HAZARDOUS, 3, II

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H336 May cause drowsiness or dizziness.

H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

· Classification according to Regulation (EC) No 1272/2008

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· Abbreviations and acronyms:

IMO: International Maritime Organization

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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

(Contd. on page 9)

Printing date 13.05.2024

Version number 7 (replaces version 6)

Revision: 13.05.2024

Trade name: IPS Margin Sealer

(Contd. of page 8)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· * Data compared to the previous version altered.