

**Safety data sheet
according to UK REACH**

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

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

- **1.1 Product identifier**
- **Trade name:** ***IPS e.max Zirconia Effect Liquid sky***
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Colouring Liquid
- **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**
Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

· **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms**



GHS05 GHS09

· **Signal word** Danger

· **Hazard-determining components of labelling:**

inorganic nitrate salts

· **Hazard statements**

H314 Causes severe skin burns and eye damage.
H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

(Contd. on page 2)

Safety data sheet according to UK REACH

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

Trade name: IPS e.max Zirconia Effect Liquid sky

(Contd. of page 1)

- **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: 16454-60-7	neodymium(III) nitrate hexahydrate	2.5-<10%
Reg.nr.: 05-2114135952-48-XXXX	Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

- **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 or oxygen; call for 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:**
Rinse out mouth and then drink plenty of water.
Seek medical treatment.
- **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 or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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:** 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).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

(Contd. on page 3)

Safety data sheet according to UK REACH

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Version number 1

Revision: 15.05.2025

Trade name: IPS e.max Zirconia Effect Liquid sky

See Section 13 for disposal information.

(Contd. of page 2)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.
Protect from heat and direct sunlight.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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:**
Keep away from foodstuffs, beverages and feed.
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.
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:** Not required.
- **Hand protection**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.



Protective gloves (EN 374)

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

- **Material of gloves**
Natural rubber, NR
Chloroprene rubber, CR
Nitrile rubber, NBR
Butyl rubber, BR
Fluorocarbon rubber (Viton)
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 4)

GB

Safety data sheet according to UK REACH

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

Trade name: IPS e.max Zirconia Effect Liquid sky

(Contd. of page 3)

· **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**

· Physical state	Fluid
· Colour:	Blue
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Flash point:	Undetermined.
· pH at 20 °C	2
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· 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 does not present an explosion hazard.
· 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	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void

(Contd. on page 5)

Safety data sheet according to UK REACH

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

Trade name: **IPS e.max Zirconia Effect Liquid sky**

(Contd. of page 4)

· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable 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.
- **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.

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.
Based on available data, the classification criteria are not met.
- **Specific symptoms in biological assay:**
- **Skin corrosion/irritation** Causes severe skin burns and eye damage.
- **Serious eye damage/irritation** Causes serious eye damage.
- **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**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

(Contd. on page 6)

GB

Safety data sheet according to UK REACH

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

Trade name: IPS e.max Zirconia Effect Liquid sky

(Contd. of page 5)

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

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.

· **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**

UN3264

· **14.2 UN proper shipping name**

· **ADR/RID/ADN**

3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)

· **IMDG, IATA**

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)

· **14.3 Transport hazard class(es)**

· **ADR/RID/ADN**



· **Class**

8 (C1) Corrosive substances.

· **Label**

8

· **IMDG**



· **Class**

8 Corrosive substances.

· **Label**

8

· **IATA**



· **Class**

8 Corrosive substances.

· **Label**

8

· **14.4 Packing group**

· **ADR/RID/ADN, IMDG, IATA**

II

· **14.5 Environmental hazards:**

· **Marine pollutant:**

Symbol (fish and tree)

· **Special marking (ADR/RID/ADN):**

Symbol (fish and tree)

(Contd. on page 7)

Safety data sheet according to UK REACH

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

Trade name: IPS e.max Zirconia Effect Liquid sky

(Contd. of page 6)

· 14.6 Special precautions for user	Warning: Corrosive substances.
· Hazard identification number (Kemler code):	80
· EMS Number:	F-A,S-B
· Segregation groups	(SGG1) Acids
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· 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	E
· IMDG	
· 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
· UN "Model Regulation":	UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (INORGANIC NITRATE SALTS), 8, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **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**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **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)

(Contd. on page 8)

Safety data sheet
according to UK REACH

Printing date 15.05.2025

Version number 1

Revision: 15.05.2025

Trade name: IPS e.max Zirconia Effect Liquid sky

(Contd. of page 7)

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

GB