

**Voluntary safety information following the Safety Data Sheet format  
according to Regulation (EC) No. 1907/2006 (REACH)**

Printing date 08.01.2021

Version number 1

Revision: 08.01.2021

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

- **1.1 Product identifier**
- **Trade name: *Fluor Protector Gel***
- **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** *Oral health care gel*
- **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@ivoclarvivadent.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**  
*The product is not classified, according to the CLP regulation.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Additional information:**  
*Cosmetics which fall under Regulation (EC) 1223/2009 are exempt from the labeling requirements of Directive 1999/45/EC and Regulation (EC) 1272/2008.*
- **Regulation (EC) No 1223/2009 on cosmetic products**  
*Contains potassium fluoride.*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
- **Description:**  
*INGREDIENTS (INCI):  
Aqua, Xylitol, Hydroxyethylcellulose, Alcohol, Potassium Fluoride, Calcium Glycerophosphate, Laureth-23,  
Panthenol, Methylparaben, Aroma, Sodium Saccharin*
- **Dangerous components:** *Void*
- **Additional information:** *For the wording of the listed hazard phrases refer to section 16.*

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(Contd. on page 2)

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(Contd. of page 1)

#### **SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Rinse with water.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **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:**  
CO<sub>2</sub>, 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** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **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** No special measures required.
- **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:** None.
- **7.3 Specific end use(s)** No further relevant information available.

#### **SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.

(Contd. on page 3)

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(Contd. of page 2)

- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

· <b>Form:</b>	Viscous
· <b>Colour:</b>	Colourless
· <b>Odour:</b>	like peppermint
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** 7.5 - 7.9

##### · Change in condition

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** Undetermined.

· **Flammability (solid, gas):** Not applicable.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

##### · Explosion limits:

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

· **Density at 20 °C:** 1.02 g/ml

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

##### · Solubility in / Miscibility with water:

Fully miscible.

· **Partition coefficient: n-octanol/water:** Not determined.

##### · Viscosity:

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

· **9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

(Contd. on page 4)

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(Contd. of page 3)

- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### **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.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### **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.

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(Contd. on page 5)

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(Contd. of page 4)

### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b> · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b> · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR/RID/ADN, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· <b>UN "Model Regulation":</b>	Void

### 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.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a cosmetic according to Regulation (EC) 1223/2009.

· **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.

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative