

## Safety data sheet

### According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

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

- **1.1 Product identifier**
- **Trade name:** FLUOCAL GEL
- **Article number / formula:** 156S
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation :** dental product
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
SEPTODONT.  
58 rue du Pont de Creteil  
94100 Saint Maur des Fosses  
France  
Téléphone: +33(0)149767000  
Fax: +33(0)148855401  
msds@septodont.com  
http://www.septodont.com
- **1.4 Emergency telephone number:**  
France (INRS 24h/24) - Tel : +33 (0)1 45 42 59 59  
Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112  
Belgique - Tel : 32 070/245 245  
UK : Call NHS 999 in a medical emergency. If you urgently need medical help or advice but it's not a life-threatening situation, call 111 (24/7). The NHS 111 number is currently only available in certain areas. If you're outside of these areas, you should call NHS Direct on 0845 4647

### SECTION 2: Hazards identification

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



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
sodium fluoride
- **Hazard statements**  
H302 Harmful if swallowed.
- **Precautionary statements**  
P264 Wash hands thoroughly after handling.

(Contd. on page 2)

GB

## Safety data sheet

### According to 1907/2006/EC, Article 31

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Version number 3

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**Trade name: FLUOCAL GEL**

(Contd. of page 1)

**P301+P312 IF SWALLOWED:** Call a POISON CENTER/doctor if you feel unwell.

**P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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:** Mixture: consisting of the following components.

#### · **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5 RTECS: KQ 6300000 Reg.nr.: 01-2119457610-43-xxxx	ethanol ⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319	<5%
CAS: 7681-49-4 EINECS: 231-667-8 Index number: 009-004-00-7	sodium fluoride ⚠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319	<5%

- **SVHC** No
- **Additional information:** For the wording of the listed risk phrases, refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After excessive inhalation:** Provide fresh air; consult a doctor in case of medical complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult a 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 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.

(Contd. on page 3)



## Safety data sheet

According to 1907/2006/EC, Article 31

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Version number 3

Revision: 09.04.2018

**Trade name: FLUOCAL GEL**

(Contd. of page 2)

**· 6.2 Environmental precautions:**

Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow the product to enter sewers/ surface water 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 :**

No dangerous substances are released.  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protective 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:** No special requirements.
- **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 section 7.

**· 8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

**CAS: 64-17-5 ethanol (<5%)**

WEL (Great Britain)	Long-term value: 1920 mg/m <sup>3</sup> , 1000 ppm
MAK (Switzerland)	Short-term value: 1920 mg/m <sup>3</sup> , 1000 ppm Long-term value: 960 mg/m <sup>3</sup> , 500 ppm SSc;

**CAS: 7664-38-2 phosphoric acid (<1%)**

WEL (Great Britain)	Short-term value: 2 mg/m <sup>3</sup> Long-term value: 1 mg/m <sup>3</sup>
IOELV (EU)	Short-term value: 2 mg/m <sup>3</sup> Long-term value: 1 mg/m <sup>3</sup>
MAK (Switzerland)	Short-term value: 2 mg/m <sup>3</sup> Long-term value: 1 mg/m <sup>3</sup> SSc;

**· DNELs****CAS: 64-17-5 ethanol**

Dermal	DNEL Worker long-term systemic	343 mg/kg bw/d
Inhalative	DNEL Worker long-term systemic	950 mg/m <sup>3</sup>
	DNEL Worker acute/short-term local effects	19 mg/m <sup>3</sup>

(Contd. on page 4)

## Safety data sheet

### According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

**Trade name: FLUOCAL GEL**

(Contd. of page 3)

#### · PNECs

##### CAS: 64-17-5 ethanol

PNEC STP	0.72 mg/L
PNEC aqua (fresh water)	0.96 mg/L
PNEC aqua (marine water)	0.79 mg/L
PNEC sediment (fresh water)	3.6 mg/kg
PNEC sediment (marine water)	2.9 mg/kg
PNEC soil	0.63 mg/kg

#### · Additional information:

The most current valid lists have been used as a basis for the production of this document.

#### · 8.2 Exposure controls

##### · Personal protective equipment:

##### · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

##### · Respiratory protection: Not required.

##### · Protection of hands:



Protective gloves

##### · Gloves material : Butyl rubber, BR

##### · Eye protection:



Safety glasses

## SECTION 9: Physical and chemical properties

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

#### · General Information

##### · Appearance:

Form:	Liquid
Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.

· pH-value: 3.5-4.5

#### · Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Ignition temperature: Not applicable.

· Decomposition temperature: Not determined.

(Contd. on page 5)



**Safety data sheet**  
**According to 1907/2006/EC, Article 31**

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

**Trade name: FLUOCAL GEL**

(Contd. of page 4)

· <b>Auto-ignition temperature:</b>	Product is not self igniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b> <b>Lower:</b> <b>Upper:</b>	Not determined. Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density:</b> · <b>Relative density :</b> · <b>Vapour density :</b> · <b>Evaporation rate :</b>	Not determined. Not determined. Not determined. Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Segregation coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b> <b>Dynamic at 20 °C:</b> <b>Kinematic:</b>	6000-12000 mPas Not determined.
· <b>Solvent content:</b> <b>VOC (EC)</b>	2.92 %
· <b>9.2 Other information :</b>	No further relevant information available.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **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:** No dangerous decomposition products known.

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity**  
Harmful if swallowed.

**LD/LC50 values relevant for classification:****CAS: 64-17-5 ethanol**

Oral	LD50	7,060 mg/kg (rat)
Inhalative	LC50/4 h	20,000 mg/l (rat)

**CAS: 7681-49-4 sodium fluoride**

Oral	LD50	52 mg/kg (rat)
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- **Primary irritant effect:**
- **On the skin:** Based on available data, the classification criteria are not met.
- **On the eyes:** Based on available data, the classification criteria are not met.

(Contd. on page 6)

## Safety data sheet

### According to 1907/2006/EC, Article 31

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Version number 3

Revision: 09.04.2018

**Trade name: FLUOCAL GEL**

(Contd. of page 5)

- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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:**

##### **CAS: 64-17-5 ethanol**

EC50 72h 275 mg/l (Algae)

EC50 48h 12,340 mg/l (daphnia)

EC50 96h 13,000 mg/l (fish)

##### **CAS: 7681-49-4 sodium fluoride**

LC50 96h &gt;530 mg/l (fish)

EC50 48h 338 mg/l (daphnia)

- **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** : Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Not classified as hazardous for transport
- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Not classified as hazardous for transport

(Contd. on page 7)





**Safety data sheet**  
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(Contd. of page 6)

- |  |   |
|--|---|
| · <b>14.3 Transport hazard class(es)</b>   |   |
| · <b>ADR, ADN, IMDG, IATA</b>  |   |
| · <b>Class</b>   | Not classified as hazardous for transport |
| · <b>14.4 Packing group</b>  |   |
| · <b>ADR, IMDG, IATA</b>   | Not classified as hazardous for transport |
| · <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>UN "Model Regulation":</b>  | Not classified as hazardous for transport |

**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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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.  
H301 Toxic if swallowed.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.

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

Acute toxicity - oral

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:**

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)  
VOC: Volatile Organic Compounds (USA, EU)  
DNEL: Derived No-Effect Level (REACH)  
PNEC: Predicted No-Effect Concentration (REACH)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
SVHC: Substances of Very High Concern

(Contd. on page 8)



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vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 2: Flammable liquids – Category 2  
Acute Tox. 3: Acute toxicity – Category 3  
Acute Tox. 4: Acute toxicity – Category 4  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

(Contd. of page 7)

GB