

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

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

- **1.1 Product identifier**
- **Trade name: R4**
- **Article number / formula: 281S**
- **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 : +44 (0)-870-190-6777 (CARECHEM24)

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.

- **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**



- **Signal word** Danger
- **Hazard statements**
H225 Highly flammable liquid and vapour.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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- **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	25-50%
CAS: 18472-51-0 EINECS: 242-354-0 Reg.nr.: 01-2119946568-22-0001	D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) ⚠ Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1)	<0.25%

- **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**
- **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:**
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:**
Dilute with plenty of water.
Do not allow the product to enter sewers/ surface water or ground water.

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- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **6.4 Reference to other sections :**
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 :**
Keep receptacles tightly sealed.
Keep away from heat and direct sunlight.
- **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.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
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

- **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 (25-50%)

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

CAS: 64-19-7 acetic acid (<0.1%)

IOELV (EU)	Short-term value: 50 mg/m ³ , 20 ppm Long-term value: 25 mg/m ³ , 10 ppm
MAK (Switzerland)	Short-term value: 50 mg/m ³ , 20 ppm Long-term value: 25 mg/m ³ , 10 ppm SSc;

· **DNELs**

CAS: 64-17-5 ethanol

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

· **PNECs**

CAS: 64-17-5 ethanol

Oral	PNEC sediment (fresh water)	3.6 mg/kg
	PNEC STP	0.72 mg/L
	PNEC aqua (fresh water)	0.96 mg/L
	PNEC aqua (marine water)	0.79 mg/L
	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:** Wash hands before breaks and at the end of work.

· **Respiratory protection:** Not required.

· **Protection of hands:** Not required.

· **Gloves material :** -

· **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Liquid
Colour:	Colourless
Odour:	Pungent
Odour threshold:	Not determined.

· **pH-value at 20 °C:** 4.3-5.3

· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	78 °C

· **Flash point:** 13 °C

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

· **Ignition temperature:** 425 °C

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not self igniting.

· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Explosion limits:**

Lower:	3,5 Vol %
Upper:	15,0 Vol %

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· Vapour pressure at 20 °C:	59 hPa
· Density at 20 °C:	0.94-0.95 g/cm ³
· Relative density :	Not determined.
· Vapour density :	Not determined.
· Evaporation rate :	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	40.03 %
· 9.2 Other information :	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 Based on available data, the classification criteria are not met.

· 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: 18472-51-0 D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

- 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.
- 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.

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- **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: 18472-51-0 D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

LC50 96h 2.08 mg/l (fish)

EC50 72h 0.081 mg/l (Algae)

EC50 48h 0.087 mg/l (Crustaceans)

· **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 :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

HP 3 Flammable

HP 4 Irritant - skin irritation and eye damage

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	UN1170
· 14.2 UN proper shipping name · ADR · IMDG · IATA	UN1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) ETHANOL SOLUTION
· 14.3 Transport hazard class(es) · ADR	
	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
	
· Class · Label	3 Flammable liquids. 3
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E, S-E A
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ)	1L

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· 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 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, 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.
- **Seveso category P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **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.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

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

Flammable liquids | Bridging principles

- **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
 vPvB: very Persistent and very Bioaccumulative
 Flam. Liq. 2: Flammable liquids – Category 2
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 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