

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

Printing date 09.06.2017

Version number 2

Revision: 09.06.2017

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)	≤1%

- **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:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· Gloves material :

The selection of suitable gloves does not depend only on the material, but also on further marks of quality which may vary 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 before use.

· Eye protection:


Tightly sealed goggles

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

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· Decomposition temperature:	<i>Not determined.</i>
· Auto-ignition temperature:	<i>Product is not self igniting.</i>
· Explosive properties:	<i>Product is not explosive. However, formation of explosive air/vapour mixtures are possible.</i>
· Explosion limits:	
Lower:	<i>3.5 Vol %</i>
Upper:	<i>15.0 Vol %</i>
· Vapour pressure at 20 °C:	<i>59 hPa</i>
· Density at 20 °C:	<i>0.94-0.95 g/cm³</i>
· Relative density :	<i>Not determined.</i>
· Vapour density :	<i>Not determined.</i>
· Evaporation rate :	<i>Not determined.</i>
· Solubility in / Miscibility with water:	<i>Fully miscible.</i>
· Segregation coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not determined.</i>
Kinematic:	<i>Not determined.</i>
· Solvent content:	
COV :	<i>40.0 %</i>
VOC (EC)	<i>40.03 %</i>
· 9.2 Other information :	<i>No further relevant information available.</i>

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	7060 mg/kg (rat)
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Inhalative	LC50/4 h	20000 mg/l (rat)
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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	>2000 mg/kg (rat)
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Dermal	LD50	>2000 mg/kg (rabbit)
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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.
- **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 12340 mg/l (daphnia)

EC50 96h 13000 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 2 (German Regulation) (Self-assessment): hazardous for water



Do not allow product to reach ground water, water course or sewage system.

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

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects :** No further relevant information available.

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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.

- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· 14.1 UN-Number	UN1170
· ADR, IMDG, IATA	
· 14.2 UN proper shipping name	UN1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· ADR	
· IMDG	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· IATA	ETHANOL SOLUTION
· 14.3 Transport hazard class(es)	
· ADR	
	
· Class	3 (F1) Flammable liquids.
· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	II
· ADR, IMDG, IATA	
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	33
· EMS Number:	F-E, S-E
· Stowage Category	A

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· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· 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)	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 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.

· **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)

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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

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