

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

Printing date 09.06.2021

Version number 1

Revision: 13.11.2020

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

· **1.1 Product identifier**

· **Trade name: R4+**

· **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:**

Distribué par :

SEPTODONT

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94100 Saint Maur des Fosses

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Fabriqué par :

Inter-Med, Inc. / Vista Dental Products

2200 South Street

Racine, WI 53404

T: (877)-418-4782

· **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

Belgium - Brüssel: +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 :**



Eye Irrit. 2 H319 Causes serious eye irritation.

Aquatic Chronic 3 H412 Harmful 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 CLP regulation.

· **Hazard pictograms**



GHS07

· **Signal word Warning**

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· Hazard statements

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

P280 Wear eye protection / face protection.

P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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: 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-tetraazatetradecanediimidine (2:1) ☠ Eye Dam. 1, H318; ☠ Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1)	≤2.5%
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· 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 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. If symptoms persist, consult a doctor.

· After swallowing: Do not induce vomiting; call for medical help immediately.**· 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: Use fire extinguishing methods suitable to surrounding conditions.**· 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.

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** : Not required.
- **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).
 - Ensure adequate ventilation.
- **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 :**
 - Ensure good ventilation/exhaustion at the workplace.
 - Prevent formation of aerosols.
- **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:** Keep container tightly sealed.
- **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
 - The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.
- **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:**
 - Keep away from food, beverages and petfood.
 - Immediately remove all soiled and contaminated clothing
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.

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· **Protection of hands:**



Protective gloves

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

· **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:	Blue
· Odour:	Like chlorine
· Odour threshold:	Not determined.

· **pH-value at 20 °C:** 5-6

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	100 °C

· **Flash point:** Not applicable.

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

· **Ignition temperature:** Not applicable.

· **Decomposition temperature:** Not determined.

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

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

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· Density at 20 °C:	1.01 g/cm ³
· Relative density :	Not determined.
· Vapour density :	Not determined.
· Evaporation rate :	Not determined.

· **Solubility in / Miscibility with water:** Not miscible or difficult to mix.

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· **Dynamic:** Not determined.

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Kinematic:	Not determined.
· Solvent content:	
COV (USA) :	0.00 %
VOC (EC)	0.00 %
· 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 :** Reacts with acids, alkalis and oxidising agents.
- **10.4 Conditions to avoid :** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
Nitrogen oxides (NO_x)
Hydrogen chloride (HCl)
Carbon monoxide and carbon dioxide

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: 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:**
Causes serious eye irritation.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **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.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

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.

· **Ecotoxicological effects:**

· **Remark:** Harmful to fish

· **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.

Harmful to aquatic organisms

· **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.

· **Uncleaned packaging:**

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

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

Not classified as hazardous for transport

· **14.2 UN proper shipping name**

· **ADR, IMDG, IATA**

Not classified as hazardous for transport

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|--|---|
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not classified as hazardous for transport |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Not classified as hazardous for transport |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | 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.
- **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

- H318 Causes serious eye damage.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

- ADR: Accord relatif au transport international 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)
- 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
- 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
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3