



Printing date 28.08.2020 Version number 1 Revision: 28.08.2020

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

· 1.1 Product identifier

· Trade name: RTR+ 80/20

· 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

 $T\'{e}l\'{e}phone: +33(0)149767000$

Fax: +33(0)148855401 msds@septodont.com

http://www.septodont.com

Provider:

BIOMATLANTE

ZA Les Quatre Nations

5 Rue Edouard Belin,

44360 Vigneux de Bretagne

France

· 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 / Luxembourg : (+352) 8002-5500

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
- $\cdot \textit{Classification according to Regulation (EC) No 1272/2008:} \\$

The product is not classified, according to the CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Not classified as hazardous
- · Hazard pictograms Not classified as hazardous
- · Signal word Not classified as hazardous
- · Hazard statements Not classified as hazardous
- · 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.

(Contd. on page 2)



Printing date 28.08.2020 Version number 1 Revision: 28.08.2020

Trade name: RTR+80/20

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· Dangerous components:					
CAS: 1306-06-5 EINECS: 215-145-7	Hydroxylapatite (Ca5(OH)(PO4)3)	20%			
	tricalcium bis(orthophosphate), with afluorine content of less than $0.005~\%$ byweight on the dry anhydrous product	80%			

- · 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 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: 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.

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: Pick up mechanically.
- · 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: Prevent formation of dust.
- · 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.

(Contd. on page 3)





Printing date 28.08.2020 Version number 1 Revision: 28.08.2020

Trade name: RTR+ 80/20

(Contd. of page 2)

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- \cdot 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:

The product does not contain any signifiant 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:

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

- · Respiratory protection: Not required.
- Protection of hands:



Protective gloves

- · Gloves material: Nitrile rubber, NBR
- · Eye protection:



Safety glasses

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Solid

Colour: According to product specification

Odour: CharacteristicOdour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not determined.

· Ignition temperature: Not applicable.

(Contd. on page 4)





Printing date 28.08.2020 Version number 1 Revision: 28.08.2020

Trade name: RTR+80/20

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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 applicable.	
· Density:	Not determined.	
· Relative density:	Not determined.	
· Vapour density:	Not applicable.	
· Evaporation rate:	Not applicable.	
· Solubility in / Miscibility with		
water:	Insoluble.	
· Segregation coefficient (n-octanol/w	vater): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Kinematic:	Not applicable.	
· 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
- $\cdot \textbf{\textit{Acute toxicity \textit{Based on available data, the classification criteria are not \textit{met.}}\\$
- · 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.

(Contd. on page 5)





Printing date 28.08.2020 Version number 1 Revision: 28.08.2020

Trade name: RTR+80/20

(Contd. of page 4)

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

SECTION 14: Transport information	n
· 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
· 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:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex I Marpol and the IBC Code	II of Not applicable.
· UN ''Model Regulation'':	Not classified as hazardous for transport

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Printing date 28.08.2020 Version number 1 Revision: 28.08.2020

Trade name: RTR+80/20

(Contd. of page 5)

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.

· 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 SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

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