



Safety data sheet

according to 1907/2006/EC, Article 31 & 2023/707/EC

Printing date 15.11.2024

Version number 1

Revision: 13.11.2024

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

· 1.1 Product identifier

· Trade name: **PARCAN L**

· Article number / formula: N163

· 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 : Medical device for dental use

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Distributed by :

SEPTODONT

58 rue du Pont de Creteil

94100 Saint Maur des Fosses

France

Phone: +33(0)149767000

msds@septodont.com

<http://www.septodont.com>

Manufactured by :

Magnum Dental OÜ

Aardla 13, 50112 Tartu, Estonia

· 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

Swiss Toxicological Information Centre (Zürich) : +41 44 251 51 51 / www.toxi.ch.

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

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



GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.



GHS09 environment

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Aquatic Acute 1 H400 Very toxic to aquatic life.

· **Additional information:**

This Regulation shall not apply to substances and mixtures in the following finished forms intended for the end user

(a) medicinal products, as defined in Directive 2001/83/EC

(b) medical devices, as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;

· **2.2 Label elements**

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

The product is classified and labelled according to the C.L.P. regulation.

· **Hazard pictograms**



GHS05 GHS09

· **Signal word** Danger

· **Hazard-determining components of labelling:**

sodium hypochlorite, solution

· **Hazard statements**

H314 Causes severe skin burns and eye damage.

H400 Very toxic to aquatic life.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection / face protection.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P310 Immediately call a POISON CENTER/doctor.

· **Additional information:**

EUH031 Contact with acids liberates toxic gas.

· **2.3 Other hazards**

The mixture shall not contain substances listed in accordance with Article 59(1) R.E.A.C.H as having endocrine disrupting properties, or be recognised as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 in a concentration equal to or greater than 0.1%.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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- **Determination of endocrine-disrupting properties** No further information available

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

- **Description:** Preparation: composed of the substances listed below.

· **Dangerous components:**

CAS: 7681-52-9	sodium hypochlorite, solution	≥5%
EINECS: 231-668-3	⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400 (M=10), EUH031	
Index number: 017-011-00-1	Specific concentration limit: EUH031: C ≥ 5 %	
Reg.nr.: 01-2119488154-34		

- **SVHC** Not applicable

- **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:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
In case of unconsciousness place patient in a stable laying down side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Do not induce vomiting; call for medical help immediately.
Drink plenty of water and provide fresh air. Call for a doctor immediately.

· 4.2 Most important symptoms and effects, both acute and delayed :

No further relevant information is available.

· 4.3 Indication of any immediate medical attention and special treatment needed :

No further relevant information is 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:** Mouth respiratory protective device.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures :

Wear a respiratory protective device.

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Wear protective equipment. Keep unprotected persons away.

· 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).
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
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:** Do not store together with acids.
- 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**· 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

- Appropriate engineering controls** No further data; see section 7.
- Individual protection measures, such as personal protective equipment**
- General protective and hygienic measures:**
Keep away from food, beverages and petfood.

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- 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:** No special measures required.
- **Hand protection**



Protective gloves

- **Gloves material :** Butyl rubber, BR
- **Eye/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Liquid
- **Form:** Liquid
- **Colour:** Light yellow
- **Odour:** Like chlorine
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH at 20 °C** 11.5-13.5
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Fully miscible.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not determined.
- **Density and/or relative density**
- **Density at 20 °C:** 1.017-1.117 g/cm³
- **Relative density :** Not determined.

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- **Vapour density :** Not determined.
- **9.2 Other information :**
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not self igniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent content:**
- **VOC (EC)** 0.00 %
- **Change in condition**
- **Evaporation rate :** Not determined.
- **Information with regard to physical hazard classes**
- **Explosives** Not classified as hazardous
- **Flammable gases** Not classified as hazardous
- **Aerosols** Not classified as hazardous
- **Oxidising gases** Not classified as hazardous
- **Gases under pressure** Not classified as hazardous
- **Flammable liquids** Not classified as hazardous
- **Flammable solids** Not classified as hazardous
- **Self-reactive substances and mixtures** Not classified as hazardous
- **Pyrophoric liquids** Not classified as hazardous
- **Pyrophoric solids** Not classified as hazardous
- **Self-heating substances and mixtures** Not classified as hazardous
- **Substances and mixtures, which emit flammable gases in contact with water** Not classified as hazardous
- **Oxidising liquids** Not classified as hazardous
- **Oxidising solids** Not classified as hazardous
- **Organic peroxides** Not classified as hazardous

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|----------------------------------|-----------------------------|
| · Corrosive to metals | Not classified as hazardous |
| | Not classified as hazardous |
| · Desensitised explosives | Not classified as hazardous |
| | Not classified as hazardous |

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 reducing agents.
Reacts with strong acids 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:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
CAS: 7681-52-9 sodium hypochlorite, solution
Oral LD50 5,800 mg/kg (mouse)
- **Primary irritant effect:**
- **On the skin:** Causes severe skin burns and eye damage.
- **On the eyes:** Causes serious eye damage.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties**
None of the ingredients is listed.

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.

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- **12.4 Mobility in soil** : No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT**: Not applicable.
- **vPvB**: Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** : No further relevant information available.
- **Remark**: Very toxic for 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.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

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

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

Throwing away bigger amounts into drains or aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the diluted product used, the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only slightly polluting for water.

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**

HP8 Corrosive

HP12 Release of an acute toxic gas

HP14 Ecotoxic

- **Uncleaned packaging**:
- **Recommendation**: Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **DOT, ADR, IMDG, IATA** UN1791
- **14.2 UN proper shipping name**
- **ADR** UN1791 HYPOCHLORITE SOLUTION, ENVIRONMENTALLY HAZARDOUS

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- **IMDG**
- **IATA**
- **14.3 Transport hazard class(es)**

HYPOCHLORITE SOLUTION, MARINE POLLUTANT
HYPOCHLORITE SOLUTION

- **ADR**



- **Class**
- **Label**

8 (C9) Corrosive substances.
8

- **IMDG**



- **Class**
- **Label**

8 Corrosive substances.
8

- **IATA**



- **Class**
- **Label**
- **14.4 Packing group**
- **ADR, IMDG, IATA**
- **14.5 Environmental hazards:**
- **Marine pollutant:**
- **Special marking (ADR):**
- **14.6 Special precautions for user**
- **Hazard identification number (Kemler code):**
- **EMS Number:**
- **Segregation groups**
- **Stowage Category**
- **Segregation Code**
- **14.7 Maritime transport in bulk according to IMO instruments**

8 Corrosive substances.
8
III
No
Symbol (fish and tree)
Symbol (fish and tree)
Warning: Corrosive substances.
80
F-A,S-B
(SGG8) Hypochlorites
B
SG20 Stow "away from" SGG1-acids
Not applicable.

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· Transport/Additional information:**· ADR**

- Limited quantities (LQ)
- Excepted quantities (EQ)

5L

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

- Transport category

3

- Tunnel restriction code

E

· IMDG

- Limited quantities (LQ)
- Excepted quantities (EQ)

5L

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

- UN "Model Regulation":

UN 1791 HYPOCHLORITE SOLUTION, 8, III,
ENVIRONMENTALLY HAZARDOUS**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

- Poisons Act

- Regulated explosives precursors

None of the ingredients is listed.

- Regulated poisons

None of the ingredients is listed.

- Reportable explosives precursors

None of the ingredients is listed.

- Reportable poisons

All substances have the value *.

- Directive 2012/18/EU

- Named dangerous substances - ANNEX I None of the ingredients is listed.

- Seveso category E1 Hazardous to the Aquatic Environment

- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t

- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

- **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.

- REGULATION (EU) 2019/1148

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

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Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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.

Classification in accordance with Delegated Regulation (EU) 2022/692 of 16 February 2022 adapting to technical and scientific progress C.L.P for the 18th time and amending table 3 of Annex VI part 3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1434 of 25 April 2023 adapting to technical and scientific progress for the 19th time C.L.P and amending Annex VI part 1, section 1.1.3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1435 of 2 May 2023 adapting to technical and scientific progress for the 20th time C.L.P and amending Annex VI part 3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2024/197 of 19 October 2023 adapting to technical and scientific progress for the 21st time C.L.P and amending Annex VI part 3 of Regulation (EC) 1272/2008.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2023/707.

Relevant phrases

H314 Causes severe skin burns and eye damage.

H400 Very toxic to aquatic life.

EUH031 Contact with acids liberates toxic gas.

Classification according to Regulation (EC) No 1272/2008

Skin corrosion/irritation

Serious eye damage/irritation

Hazardous to the aquatic environment - short-term
(acute) aquatic hazard

The classification of the mixture is generally based
on the calculation method using substance data
according to Regulation (EC) No 1272/2008.

Date of previous version: 01.03.2022**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

DOT: US Department of Transportation

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)

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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

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

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