

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

Printing date 18.01.2021

Version number 1

Revision: 18.01.2021

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

· **1.1 Product identifier**

· **Trade name:** *Largal +*

· **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

58 rue du Pont de Creteil

94100 Saint Maur des Fosses

France

Téléphone: +33(0)149767000

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http://www.septodont.com

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

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**

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



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

· **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

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- **Signal word** Warning
- **Hazard-determining components of labelling:**
acide éthylènediaminetétraacétique disodique-dihydrate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
- **Precautionary statements**
P264 Wash thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
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: 6381-92-6 | acide éthylènediaminetétraacétique disodique-dihydrate ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | 10-25% |
| CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6 Reg.nr.: 01-2119457892-27 | sodium hydroxide ⚠ Met. Corr.1, H290; Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302 Specific concentration limits: Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0.5 % ≤ C < 2 % Eye Irrit. 2; H319: 0.5 % ≤ C < 2 % | ≤2.5% |

- **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:**
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. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult a doctor.

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- **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 :** Not required.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
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).
- **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 :** No special precautions are necessary if used correctly.
- **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:**CAS: 1310-73-2 sodium hydroxide (≤2.5%)**

| | |
|---------------------|---|
| WEL (Great Britain) | Short-term value: 2 mg/m ³ |
| MAK (Switzerland) | Short-term value: 2 e mg/m ³ Long-term value: 2 e mg/m ³ SSc; |

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· DNELs

CAS: 1310-73-2 sodium hydroxide

| | | |
|------------|-------------------------------------|---------------------|
| Inhalative | DNEL Public long-term local effects | 1 mg/m ³ |
| | DNEL Worker long-term local effects | 1 mg/m ³ |

· 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.

· 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: | According to product specification |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |

· pH-value: 6.8-7.5

· Change in condition

| | |
|---|---------------|
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |

· 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.

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| | |
|---|---|
| · 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: | 1.06 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) | 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 :** 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: 6381-92-6 *acide éthylènediaminetétraacétique disodique-dihydrate*

Oral LD50 500 mg/kg (ATE)

CAS: 1310-73-2 *sodium hydroxide*

Oral LD50 2000 mg/kg (rat)

- **Primary irritant effect:**
- **On the skin:**
Causes skin irritation.
- **On the eyes:**
Causes serious eye irritation.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.

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- **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**
May cause respiratory irritation.
- **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: 1310-73-2 sodium hydroxide

LC50 96h | 35-189 mg/l (fish)

- **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**

HP4 | Irritant - skin irritation and eye damage

HP5 | Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

- **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, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.2 UN proper shipping name · ADR, ADN, 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: · 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.
- 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.

- 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
- H290 May be corrosive to metals.
- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

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

| | |
|--|--|
| Skin corrosion/irritation Serious eye damage/eye irritation Specific target organ toxicity (single exposure) | The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008. |
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· 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)

DNEL: Derived No-Effect Level (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

Met. Corr. 1: Corrosive to metals – Category 1

Acute Tox. 4: Acute toxicity – Category 4

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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