

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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

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

- **1.1 Product identifier**
- **Trade name:** Largal ultra
- **Article number / formula:** 169S
- **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 Healthcare India Pvt. Ltd.  
C-1/2, MIDC, Taloja, Tal, Panvel, Dist Raigad  
410208- Maharashtra - INDIA  
Tel. : +91 (22) 27 40 19 70 / 71  
Fax : +91 (22) 27 40 19 72
- **1.4 Emergency telephone number:**  
France (ORFILA 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

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 :**



- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Irrit. 2 H319 Causes serious eye irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :**



Xi; Irritant

- R36/38: Irritating to eyes and skin.
- **Information concerning particular hazards for human and environment:**  
The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU" .
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **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
- **Hazard statements**  
H315 Causes skin irritation.

(Contd. on page 2)

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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

**Trade name: Largal ultra**

(Contd. of page 1)

H319 Causes serious eye irritation.

**Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P264 Wash hands thoroughly after handling.

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

P302+P352 **IF ON SKIN:** Wash with plenty of water.

**2.3 Other hazards**

**Results of PBT and vPvB assessment**

**PBT:** Not applicable.



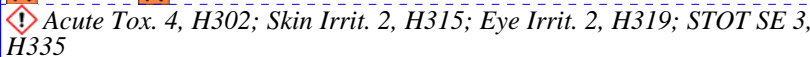





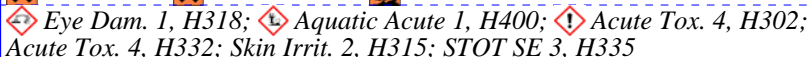


**vPvB:** Not applicable.

**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  Xn R22;  Xi R36/37/38  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	sodium hydroxide  C R35  Skin Corr. 1A, H314	≤2,5%
CAS: 1119-97-7	Trimethyltetradecyl-ammonium bromide  Xn R20/22;  Xi R37/38-41;  N R50  Eye Dam. 1, H318;  Aquatic Acute 1, H400;  Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; STOT SE 3, H335	≤1%

**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:**

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.

**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:**

CO<sub>2</sub>, 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.

(Contd. on page 3)

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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

**Trade name: Largal ultra**

(Contd. of page 2)

- **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 to enter sewers/ surface 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

- **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 significant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**
  - As a basis for the production of this document, the most current valid lists were used.
- **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

(Contd. on page 4)

IN

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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

**Trade name: Largal ultra**

(Contd. of page 3)

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 only depend 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:** According to product specification

**· Odour:** Characteristic

**· Odour threshold:** Not determined.

**· pH-value:** 6,5-7,5

**· Change in condition**

**Melting point/Melting range:** Undetermined.

**Boiling point/Boiling range:** Undetermined.

**· Flash point:** Not applicable.

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

**· Ignition temperature:** Not applicable.

**· Decomposition temperature:** Not determined.

**· Self-igniting:** Product is not self igniting.

**· Danger of explosion:** Product does not present an explosion hazard.

**· Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.

**· Vapour pressure:** Not determined.

**· Density at 20 °C:** 1,075-1,083 g/cm<sup>3</sup>

**· 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.

(Contd. on page 5)



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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

**Trade name: Largal ultra**

(Contd. of page 4)

**Kinematic:** Not determined.  
**9.2 Other information :** No further relevant information available.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity**
- **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:**

**LD/LC50 values relevant for classification:****1310-73-2 sodium hydroxide**

Oral LD50 2000 mg/kg (rat)

- **Primary irritant effect:**
- **On the skin:** Irritant to skin and mucous membranes.
- **On the eyes:** Irritating effect.
- **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:**  
The product shows the following hazards according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant

**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.

(Contd. on page 6)

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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

**Trade name: Largal ultra**

(Contd. of page 5)

**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**

- |   |   |
|---|---|
| · <b>14.1 UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | Not classified as hazardous for transport |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Not classified as hazardous for transport |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Not classified as hazardous for transport |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Not classified as hazardous for transport |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No  |
| · <b>14.6 Special precautions for user</b>  | Not applicable.                           |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>       | Not applicable.                           |
| · <b>UN "Model Regulation":</b>   | -   |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **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**
- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.

(Contd. on page 7)

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

Printing date 29.10.2014

Version number 1

Revision: 29.10.2014

**Trade name: Largal ultra**

(Contd. of page 6)

- H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H332 Harmful if inhaled.  
H335 May cause respiratory irritation.  
H400 Very toxic to aquatic life.  
.....  
R20/22 Harmful by inhalation and if swallowed.  
R22 Harmful if swallowed.  
R35 Causes severe burns.  
R36/37/38 Irritating to eyes, respiratory system and skin.  
R37/38 Irritating to respiratory system and skin.  
R41 Risk of serious damage to eyes.  
R50 Very toxic to aquatic organisms.

**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)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
Acute Tox. 4: Acute toxicity, Hazard Category 4  
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A  
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2  
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1  
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2  
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3  
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

IN