SAFETY DATA SHEET (REGULATION (EC) No 1907/2006 - REACH)  
PRODUITS DENTAIRES SA  
Name: EDTA 17% GEL - ART.11566

SAFETY DATA SHEET  
(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
Product name: EDTA 17% GEL
Product code: ART.11566.

1.2. Relevant identified uses of the substance or mixture and uses advised against
For dental professional use only.

1.3. Details of the supplier of the safety data sheet
Registered company name: PRODUITS DENTAIRES SA.
Address: Rue des Bosquets 18. 1800. Vevey. Switzerland.
info@pdsa.ch
http://www.pdsa.ch

Association/Organisation: 

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
In compliance with EC regulation No. 1272/2008 and its amendments.
Serious eye damage, Category 1 (Eye Dam. 1, H318).
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

Serious eye damage (Xi, R 41).
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements
In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms:

GHS05

Signal Word:
DANGER

Product identifiers:
EC 200-573-9 EDTA TÉTRASODIQUE DIHYDRATE

Hazard statements:
H318 Causes serious eye damage.

Precautionary statements - Prevention:
P280 Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary statements - Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards
The mixture does not contain any substances classified as 'Substances of Very High Concern' (SVHC) by the European Chemical Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table
The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS
3.1. Substances
No substances fulfil the criteria set forth in annexe II section A of the REACH regulation (EC) n° 1907/2006.

3.2. Mixtures
Composition:

<table>
<thead>
<tr>
<th>Identification</th>
<th>(EC) 1272/2008</th>
<th>67/548/EEC</th>
<th>Note</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 10378-23-1</td>
<td>GHS07, GHS05</td>
<td>Xn</td>
<td></td>
<td>10 &lt;= x % &lt; 25</td>
</tr>
<tr>
<td>EC: 200-573-9</td>
<td>Dgr</td>
<td>Xn;R22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EDTA TÉTRASODIQUE DIHYDRATE</td>
<td>Acute Tox. 4, H302</td>
<td>Xi;R41</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Eye Dam. 1, H318</td>
<td>Xn</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4 : FIRST AID MEASURES
As a general rule, in case of doubt or if symptoms persist, always call a doctor.
NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures
In the event of splashes or contact with eyes:
Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.
Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

In the event of splashes or contact with skin:
Wash the skin thoroughly with soap and fresh water.
Be careful with product which can remain between the skin and the clothes, the watch, the jewels.
In the event of an allergic reaction, seek medical attention.

In the event of swallowing:
Seek medical attention, showing the label.
Rinse the mouth with water.

4.2. Most important symptoms and effects, both acute and delayed
No data available.

4.3. Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5 : FIREFIGHTING MEASURES
Non-flammable.

5.1. Extinguishing media
Suitable methods of extinction
In the event of a fire, use:
- sprayed water or water mist
- powder
- carbon dioxide (CO2)
- stable foams in alcohols
Unsuitable methods of extinction
In the event of a fire, do not use:
- water jet

5.2. Special hazards arising from the substance or mixture
A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.
Do not breathe in smoke.
In the event of a fire, the following may be formed:
- carbon monoxide (CO)
- carbon dioxide (CO2)
- nitrogen oxide (NO)
- nitrogen dioxide (NO2)
- sodium oxide

5.3. Advice for firefighters
Wear self-contained breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
Consult the safety measures listed under headings 7 and 8.

For non fire-fighters
Avoid any contact with the skin and eyes.

For fire-fighters
Fire-fighters will be equipped with suitable personal protective equipment (See section 8).
Avoid any contact with the skin and eyes.

6.2. Environmental precautions
Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.
Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up
Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections
No data available.

SECTION 7 : HANDLING AND STORAGE

Respect storage precautions mentioned in the instructions for use.

7.1. Precautions for safe handling
Always wash hands after handling.
The persons who have medical histories of cutaneous reactions must use this product with all the required precautions.
Avoid any contact with skin and eyes.

Fire prevention:
Prevent access by unauthorised personnel.

Recommended equipment and procedures:
For personal protection, see section 8.
Avoid eye contact with this mixture at all times.
Packages which have been opened must be reclosed carefully.

7.2. Conditions for safe storage, including any incompatibilities
Keep the container tightly closed
Storage
Respect storage precautions mentioned in the instructions for use.

Packaging
Always conserve in the original packaging.

7.3. Specific end use(s)
Consult instructions for use enclosed.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters
No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment
Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE):

- **Eye / face protection**
  Avoid contact with eyes.

- **Hand protection**
  Wear gloves according to the hygienic rules in force in dental surgeries.

- **Body protection**
  After contact with the product, all parts of the body that have been soiled must be washed.
  Avoid any contact with skin.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

**General information**:
- Physical state: paste.
- Colour: colourless
- Odour: characteristic

**Important health, safety and environmental information**
- pH (aqueous solution): 10
- pH: 10.00, slightly basic.
- Boiling point/boiling range: not relevant.
- Flash point interval: not relevant.
- Vapour pressure (50°C): not relevant.
- Density: 1.11
- Water solubility: Dilutable.
- Melting point/melting range: not relevant.
- Self-ignition temperature: not relevant.
- Decomposition point/decomposition range: not relevant.

9.2. Other information
No data available.
SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity
No data available.

10.2. Chemical stability
This mixture is stable under the recommended handling and storage conditions in section 7.
Do not use if the expiry date is exceeded.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Avoid:
- heat
- frost

10.5. Incompatible materials
Keep away from:
- strong acids
- strong oxidising agents

10.6. Hazardous decomposition products
The thermal decomposition may release/form:
- carbon monoxide (CO)
- carbon dioxide (CO2)
- nitrogen oxide (NO)
- nitrogen dioxide (NO2)
- sodium oxide

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
May have irreversible effects on the eyes, such as tissue damage in the eye, or serious physical decay of sight, which is not fully reversible by the end of observation at 21 days.

11.1.1. Substances
Acute toxicity:
EDTA TÉTRASODIQUE DIHYDRATE (CAS: 10378-23-1)
Oral route: DL50 > 630 mg/kg
Species: Rat

Serious damage to eyes/eye irritation:
EDTA TÉTRASODIQUE DIHYDRATE (CAS: 10378-23-1)
Causes serious eye damage.

Corneal haze:
Average score >= 3

Iritis:
Average score > 1.5

The substance produces at least in one animal effects on the conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days.
The substance produces at least in one animal effects on the conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days.

**Carcinogenicity :**
EDTA TÉTRASODIQUE DIHYDRATE (CAS: 10378-23-1)
Carcinogenicity Test :
Negative.
No carcinogenic effect.
Species : Human

11.1.2. Mixture
No toxicological data available for the mixture.

### SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity
12.1.2. Mixtures
No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability
No data available.

12.3. Bioaccumulative potential
No data available.

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
No data available.

12.6. Other adverse effects
No data available.

### SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods
Do not pour into drains or waterways.

**Waste :**
Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.
Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

**Soiled packaging :**
Empty container completely. Keep label(s) on container.
Give to a certified disposal contractor.

### SECTION 14 : TRANSPORT INFORMATION
Exempt from transport classification and labelling.

SECTION 15 : REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
- Classification and labelling information included in section 2:
  The following regulations have been used:
  - Directive 1999/45/EC and its adaptations
  - Regulation EC 1272/2008 modified by regulation EC 618/2012
- Container information:
  The mixture is contained in packaging that does not exceed 125 ml.
- Particular provisions:
  No data available.
- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704):
  NFPA 704, Labelling: Health=3 Inflammability=1 Instability/Reactivity=1 Specific Risk=none

15.2. Chemical safety assessment
No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.


Hazard symbols:

Contains:
EC 200-573-9 EDTA TÉTRASODIQUE DIHYDRATE

Risk phrase:
R 41 Risk of serious damage to eyes.

Safety phrase:
S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 36/39 Wear suitable protective clothing and eye/face protection.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S 60 This material and its container must be disposed of as hazardous waste.

**Title for H, EUH and R indications mentioned in section 3:**
- **H302**: Harmful if swallowed.
- **H318**: Causes serious eye damage.
- **R 22**: Harmful if swallowed.
- **R 41**: Risk of serious damage to eyes.

**Abbreviations:**
- **ADR**: European agreement concerning the international carriage of dangerous goods by Road.
- **IMDG**: International Maritime Dangerous Goods.
- **IATA**: International Air Transport Association.
- **ICAO**: International Civil Aviation Organisation
- **RID**: Regulations concerning the International carriage of Dangerous goods by rail.
- **GHS05**: Corrosion