

Name: EDTA 17% SOLUTION - ART.11565



## 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% SOLUTION

Product code : ART.11565.

#### 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.

Telephone : +41 21 921 26 31. Fax : +41 21 921 39 79.

info@pdsa.ch

http://www.pdsa.ch

#### 1.4. Emergency telephone number : +41 21 921 26 31.

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.

##### In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

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.

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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 :**

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

**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

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**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 (CO<sub>2</sub>)
- nitrogen oxide (NO)
- nitrogen dioxide (NO<sub>2</sub>)
- sodium oxide

**5.3. Advice for firefighters**

Wear self-contained breathing apparatus.

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**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.

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**SECTION 7 : HANDLING AND STORAGE**

Respect storage precautions mentioned on the packaging or 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 and stored in an upright position.

**7.2. Conditions for safe storage, including any incompatibilities**

Keep the container tightly closed

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**Storage**

Respect storage precautions mentioned on the packaging or in the instructions for use.

**Packaging**

Always conserve in the original packaging.

**7.3. Specific end use(s)**

Consult instructions for use enclosed.

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**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.

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**SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**

**9.1. Information on basic physical and chemical properties**

**General information :**

|                  |                |
|------------------|----------------|
| Physical state : | fluid liquid.  |
| Colour:          | colourless     |
| Odour:           | characteristic |

**Important health, safety and environmental information**

|                               |                                                                                                                                                                  |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| pH (aqueous solution) :       | 11                                                                                                                                                               |
| pH :                          | 11.00 .                                                                                                                                                          |
|                               | 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.                                                                                                                                                       |
| Viscosity :                   | 1.8                                                                                                                                                              |
| Viscosity:                    | v < 7 mm <sup>2</sup> /s (40°C)                                                                                                                                  |
|                               | Method for determining the viscosity :                                                                                                                           |
|                               | DIN 51562-1 (Viscometry - Measurement of kinematic viscosity by means of the Ubbelohde viscometer - Part 1: Viscometer specification and measurement procedure). |
| Melting point/melting range : | not relevant.                                                                                                                                                    |
| Self-ignition temperature :   | not relevant.                                                                                                                                                    |

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Decomposition point/decomposition range : not relevant.

**9.2. Other information**

The liquid crystallizes at low temperature, but it becomes again clear at room temperature without damage.

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**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 :

- frost
- heat

**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 (CO<sub>2</sub>)
- nitrogen oxide (NO)
- nitrogen dioxide (NO<sub>2</sub>)
- sodium oxide

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**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 : DL<sub>50</sub> > 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

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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.

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**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.

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**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.

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#### SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2013).

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#### 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 67/548/EEC and its adaptations
- Directive 1999/45/EC and its adaptations
- Regulation EC 1272/2008 modified by regulation EC 618/2012

###### - Container information:

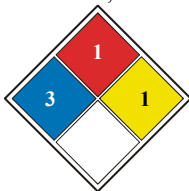
The mixture is contained in packaging that does not exceed 125 ml.

###### - 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.

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#### 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.

##### In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Hazard symbols :



Irritant

Contains :

EC 200-573-9

EDTA TÉTRASODIQUE DIHYDRATE

Risk phrase :

R 41

Risk of serious damage to eyes.

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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