

Name : **DISCLOSING TABLETS - ART.11611/12/13**



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 : DISCLOSING TABLETS

Product code : ART.11611/12/13.

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.

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

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.

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

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.

Additional labeling :

EUH210

Safety data sheet available on request.

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.

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SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
CAS: 139-05-9 CYCLAMATE DE SODIUM	GHS07 Wng Acute Tox. 4, H302	Xn Xn;R22		2.5 ≤ x % < 10
CAS: 557-04-0 EC: 209-150-3 STEARATE DE MAGNESIUM	GHS07 Wng Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Xi Xi;R36/37/38		1 ≤ x % < 2.5

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.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of swallowing :

Seek medical attention, showing the label.

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 :

- 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)

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 fire-fighters

Fire-fighters will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming).

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Respect storage precautions mentioned on the packaging and/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.

Do not swallow

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

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 and away from dampness

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.

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- Hand protection

Wear gloves according to the hygienic rules in force in dental surgeries.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	Solid.
Colour:	pink
Odour:	Menthol

Important health, safety and environmental information

pH :	Not relevant.
Boiling point/boiling range :	Not relevant.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	< 1
Water solubility :	Soluble.
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 :
- humidity

10.5. Incompatible materials

Keep away from :
- strong oxidising agents

10.6. Hazardous decomposition products

The thermal decomposition may release/form :
- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

No data available.

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11.1.1. Substances

Acute toxicity :

CYCLAMATE DE SODIUM (CAS: 139-05-9)

Oral route :

LD50 = 1280 mg/kg

Species : Rat

Carcinogenicity :

STEARATE DE MAGNESIUM (CAS: 557-04-0)

Carcinogenicity Test :

Negative.

No carcinogenic effect.

11.1.2. Mixture

No toxicological data available for the mixture.

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 139-05-9 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

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.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

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).

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
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.

- Container information:

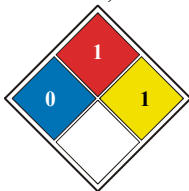
No data available.

- 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=0 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.

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

No labelling requirements for this mixture.

Risk phrase :

Safety data sheet available for professional user on request.

Title for H, EUH and R indications mentioned in section 3 :

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
R 22	Harmful if swallowed.

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R 36/37/38

Irritating to eyes, respiratory system and skin.

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.