

# **SAFETY DATA SHEET**

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

# 1.1. Product identifier

Product name: OPACAL Product code: ART.11020.

# 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:.

info@pd-dental.com https://pd-dental.com

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

Association/Organisation: .

# **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the substance or mixture

#### GHS compliant.

Skin irritation, Category 2 (Skin Irrit. 2, H315).

Serious eye damage, Category 1 (Eye Dam. 1, H318).

Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).

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

# GHS compliant.

Hazard pictograms:





GHS05

GHS07

Signal Word:

DANGER

Product identifiers:

CAS 1305-62-0 HYDROXYDE DE CALCIUM

Hazard statements:

H315 Causes skin irritation.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

Precautionary statements - Prevention:

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves according to the hygienic rules in force in dental

surgeries.

Precautionary statements - Response :

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

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a doctor/physician.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

Precautionary statements - Disposal:

P501 Dispose of contents/container according to the hygienic rules in force in dental

surgeries and according to the legislation in force.

#### 2.3. Other hazards

No data available.

# SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2. Mixtures

# **Composition:**

| Identification               | GHS                 | Note | %              |
|------------------------------|---------------------|------|----------------|
| CAS: 1305-62-0               | GHS07, GHS05        | [1]  | 25 <= x % < 50 |
| EC: 215-137-3                | Dgr                 |      |                |
| REACH: 01-2119475151-45-0023 | Skin Irrit. 2, H315 |      |                |
|                              | Eye Dam. 1, H318    |      |                |
| HYDROXYDE DE CALCIUM         | STOT SE 3, H335     |      |                |

(Full text of H-phrases: see section 16)

#### **Information on ingredients:**

[1] Substance for which maximum workplace exposure limits are available.

#### **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 fresh, 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:

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

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.

Wash the skin thoroughly with soap and fresh water.

# In the event of swallowing:

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.

Keep the person exposed at rest. Do not force vomiting.

#### 4.2. Most important symptoms and effects, both acute and delayed

Calcium hydroxide does not present acute toxicity by oral or cutaneous route or by inhalation. It is classified as irritating to skin or respiratory system and can cause serious eye damages.

Local effects (related to pH) are the main health risks.

# 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

# **SECTION 5 : FIREFIGHTING MEASURES**

Non-flammable.

The product is not combustible itself. Adapt the measures of extinction in the middle surrounding.

#### 5.1. Extinguishing media

#### Suitable methods of extinction

In the event of a fire, use:

- dry chemical agents
- carbon dioxide (CO2)

#### 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)
- sulphur dioxide (SO2)
- barium 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 first aid worker

Avoid any contact with the skin and eyes.

#### For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

Avoid any contact with the skin and eyes.

#### 6.2. Environmental precautions

Prevent any material from entering drains or waterways.

# 6.3. Methods and material for containment and cleaning up

Neutralise with an acidic decontaminant.

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 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.

# 7.2. Conditions for safe storage, including any incompatibilities

Keep in the original container, respect the storage temperatures mentioned on the container, the leaflet and the box.

#### 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.

For dental use only.

# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

# 8.1. Control parameters

# Occupational exposure limits:

- European Union (2019/1831, 2017/2398, 2017/164, 2009/161, 2006/15/CE, 2000/39/CE, 98/24/CE):

| CAS       | VME-mg/m3: | VME-ppm: | VLE-mg/m3: | VLE-ppm: | Notes: |
|-----------|------------|----------|------------|----------|--------|
| 1305-62-0 | 1          | -        | 4          | -        | -      |

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010):

| CAS       | TWA:    | STEL: | Ceiling: | Definition: | Criteria: |
|-----------|---------|-------|----------|-------------|-----------|
| 1305-62-0 | 5 mg/m3 |       |          |             |           |

- Germany - AGW (BAuA - TRGS 900, 08/08/2019) :

| CAS       | VME: | VME:    | Excess | Notes |
|-----------|------|---------|--------|-------|
| 1305-62-0 |      | 1 mg/m³ |        | 2 (I) |

- France (INRS - ED984 / 2019-1487):

| CAS       | VME-ppm: | VME-mg/m3: | VLE-ppm: | VLE-mg/m3: | Notes: | TMP No: |
|-----------|----------|------------|----------|------------|--------|---------|
| 1305-62-0 | -        | 1          | -        | 4          | -      | -       |

- UK / WEL (Workplace exposure limits, EH40/2005, 2011):

| 011/ // 11 | ornprace emposar   | •          | , =000, =011). |             |           |
|------------|--------------------|------------|----------------|-------------|-----------|
| CAS        | TWA:               | STEL:      | Ceiling:       | Definition: | Criteria: |
| 1305-62-0  | - ppm              | - ppm      |                |             |           |
|            | $5 \text{ mg/m}^3$ | $- mg/m^3$ |                |             |           |

#### 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

Avoid skin contact.

After contact with the product, all parts of the body that have been soiled must be washed.

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

# 9.1. Information on basic physical and chemical properties

# General information:

Physical state : Paste.
Colour: white

Important health, safety and environmental information

pH: Not stated.

Strongly basic.

Boiling point/boiling range:

Flash point interval:

Not relevant.

Vapour pressure (50°C):

Not relevant.

Density: 1.34

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:

- heat

# 10.5. Incompatible materials

Keep away from:

- aluminium
- acids
- phosphorus

# 10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO2)
- sulphur dioxide (SO2)
- barium oxide

# SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

May cause irreversible damage to the skin; namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

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.

Serious eye damage is typified by the destruction of cornea, persistent corneal opacity and iritis.

# 11.1.1. Substances

#### Acute toxicity:

HYDROXYDE DE CALCIUM (CAS: 1305-62-0)

Oral route : LD50 = 7340 mg/kg

Species: Rat

#### Skin corrosion/skin irritation:

HYDROXYDE DE CALCIUM (CAS: 1305-62-0)

Corrosivity: No observed effect.

Effect observed: Overall irritation score

#### Serious damage to eyes/eye irritation:

HYDROXYDE DE CALCIUM (CAS: 1305-62-0)

The substance produces at least in one animal effects on the cornea 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 iris 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.

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.

# Respiratory or skin sensitisation:

HYDROXYDE DE CALCIUM (CAS: 1305-62-0)

Local lymph node stimulation test : Non-Sensitiser.

Guinea Pig Maximisation Test (GMPT): Non-sensitiser.

Buehler Test: Non-sensitiser.

# 11.1.2. Mixture

No toxicological data available for the mixture.

# SECTION 12 : ECOLOGICAL INFORMATION

# 12.1. Toxicity

# 12.1.1. Substances

HYDROXYDE DE CALCIUM (CAS: 1305-62-0)

Fish toxicity: LC50 = 160 mg/l

Species : Gambusia affinis Duration of exposure : 96 h

# **12.1.2.** Mixtures

No aquatic toxicity data available for the mixture.

# 12.2. Persistence and degradability

# 12.2.1. Substances

HYDROXYDE DE CALCIUM (CAS: 1305-62-0)

Biodegradability: no degradability data is available, the substance is considered as not degrading

quickly.

#### 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

The appropriate waste management of the mixture and/or its container must be determined in accordance with local regulations.

# 13.1. Waste treatment methods

Do not pour into drains or waterways.

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.

# SECTION 14: TRANSPORT INFORMATION

Exempt from transport classification and labelling.

### 14.1. UN number

# 14.2. UN proper shipping name

# 14.3. Transport hazard class(es)

# 14.4. Packing group

# 14.5. Environmental hazards

# 14.6. Special precautions for user

#### SECTION 15: REGULATORY INFORMATION

# 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

The following regulations have been used:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), review no. 7 (2017)

#### - Container information:

The mixture is packed in an interior packaging, not exceeding 10 ml, the required labelling elements appear on the outer packaging.

# - 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.

# Wording of the phrases mentioned in section 3:

H315 Causes skin irritation.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

# 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

GHS07: Exclamation mark

PBT: Persistent, bioaccumulable and toxic. vPvB : Very persistent, very bioaccumulable.