

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: OPACAL

Manufacturer: PRODUITS DENTAIRES SA.

SDS Expiry: 31 August 2025

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6 / 8

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – August 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

OPACAL - ART.11020_GHS



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/...

OPACAL - ART.11020_GHS

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

(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.

OPACAL - ART.11020_GHS

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.

OPACAL - ART.11020_GHS

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/m ³	VME-ppm	VLE-mg/m ³	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/m ³				

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

CAS	VME :	VME / m ³	Excess	Notes
1305-62-0		1 mg/m ³		2 (I)

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

CAS	VME-ppm :	VME-mg/m ³	VLE-ppm :	VLE-mg/m ³	Notes :	TMP No :
1305-62-0	-	1	-	4	-	-

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1305-62-0	- ppm 5 mg/m ³	- ppm - 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

OPACAL - ART.11020_GHS

Important health, safety and environmental information

pH :	Not stated.
	Strongly basic.
Boiling point/boiling range :	Not relevant.
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

OPACAL - ART.11020_GHS

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.

OPACAL - ART.11020_GHS

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 :

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.

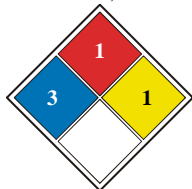
- Particular provisions :

No data available.

OPACAL - ART.11020_GHS

- 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.