SAFETY DATA SHEET

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

1.1. Product identifier

Product name : PULPOTEC POWDER

Product code : ART.11563.

1.2. Relevant identified uses of the substance or mixture and uses advised against

For dental professional use only.

To mix with PULPOTEC LIQUID

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.

Acute oral toxicity, Category 5 (Acute Tox. 5, H303).

Acute inhalation toxicity, Category 5 (Acute Tox. 5, H333).

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

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

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

Germ cell mutagenicity, Category 2 (Muta. 2, H341).

Carcinogenicity, Category 1B (Carc. 1B, H350).

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

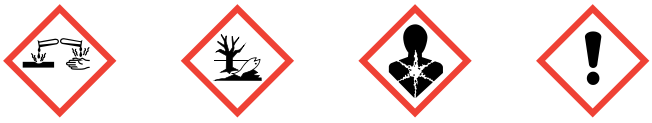
Hazardous to the aquatic environment - Chronic hazard, Category 1 (Aquatic Chronic 1, H410).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

GHS compliant.

Hazard pictograms :



GHS05 GHS09 GHS08 GHS07

Signal Word :

DANGER

Product identifiers :

CAS 75-47-8 IODOFORME

CAS 30525-89-4 POLYOXYMETHYLENE

Hazard statements :

H303 + H333	May be harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.

H341	Suspected of causing genetic defects .
H350	May cause cancer .
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements - Prevention :	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust and vapours.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
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
P304 + P312	IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P391	Collect spillage.
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

In use, may form flammable/explosive dust-air mixture.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	Classification GHS	Note	%
CAS: 1314-13-2 EC: 215-222-5 REACH: 01-2119463881-32 ZINC OXIDE	GHS09 Wng Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1	[i]	50 <= x % < 100
CAS: 75-47-8 EC: 200-874-5 IODOFORME	GHS07, GHS09 Wng Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 4, H332 STOT SE 3, H335 Aquatic Chronic 2, H411	[i]	10 <= x % < 25
CAS: 30525-89-4 POLYOXYMETHYLENE	GHS07, GHS05, GHS08 Dgr Acute Tox. 4, H302 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Muta. 2, H341 Carc. 1B, H350	[ii]	2.5 <= x % < 10

CAS: 50-00-0 EC: 200-001-8 FORMALDEHYDE 40%	GHS06, GHS05, GHS07, GHS08 Dgr Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 Acute Tox. 2, H330 STOT SE 3, H335 Muta. 2, H341 Carc. 1B, H350 STOT SE 1, H370	[i] [ii]	0 <= x % < 1

Information on ingredients :

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

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

[ii] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

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 exposure by inhalation :

In the event of massive inhalation of dust, remove the person exposed to fresh air. Keep warm and at rest.

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.

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

In the event of splashes or contact with skin :

In the event of an allergic reaction, seek medical attention.

If the contaminated aera 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.

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, administer activated medical charcoal and consult a doctor.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

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

Breathing system irritation.

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

In case of very important inhalation of vapors and very strong irritation of lungs, treat with Dexamethasone in spray.

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
- foam

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)
- metallic oxide smokes
- formaldehyde vapors
- halogenic compounds

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.

Avoid inhaling dust.

If a large quantity has been spilt, evacuate all personnel and only allow intervention by trained operators equipped with safety apparatus.

Avoid generating dusts.

For first aid worker

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

Avoid generating dusts.

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

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

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 inhaling dust.

Avoid eye contact with this mixture at all times.

Packages which have been opened must be reclosed carefully and stored in an upright position.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

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

Keep the well closed bottle.

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

Occupational exposure limits :

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1314-13-2	2 (R) mg/m3	10 (R) mg/m3			
75-47-8	0.6 ppm				
50-00-0			0.3 ppm	SEN; A2	

- UK :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
75-47-8	0.6 ppm 9.8 mg/m3	1 ppm 16 mg/m3			
50-00-0	2 ppm 2.5 mg/m3	2 ppm 2.5 mg/m3		Carc	

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.

- Respiratory protection

Avoid inhaling dust.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

No data available.

Physical state

Physical state : Powder or dust.

Colour

Colour: Yellowish

Odour

Odour threshold : Not stated.

Odour Pungent (presence of polyoxymethylene)

Melting point

Melting point/melting range : Not relevant.

Freezing point

Freezing point / Freezing range : Not stated.

Boiling point or initial boiling point and boiling range
Boiling point/boiling range : Not relevant.

Flammability
Flammability (solid, gas) : Not stated.

Lower and upper explosion limit
Explosive properties, lower explosivity limit (%) : Not stated.
Explosive properties, upper explosivity limit (%) : Not stated.

Flash point
Flash point interval : Not relevant.

Auto-ignition temperature
Self-ignition temperature : Not relevant.

Decomposition temperature
Decomposition point/decomposition range : Not relevant.

pH
pH (aqueous solution) : Not stated.
pH : Not relevant.

Kinematic viscosity
Viscosity : Not stated.

Solubility
Water solubility : Insoluble.
Fat solubility : Not stated.

Partition coefficient n-octanol/water (log value)
Partition coefficient: n-octanol/water : Not stated.

Vapour pressure
Vapour pressure (50°C) : Not relevant.

Density and/or relative density
Density : 0.85

Relative vapour density
Vapour density : Not stated.

9.2. Other information
No data available.

9.2.1. Information with regard to physical hazard classes
No data available.

9.2.2. Other safety characteristics
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 :
- formation of dusts
- heat
- exposure to light

Dusts can form an explosive mixture with air.

10.5. Incompatible materials

Keep away from :

- acids
- strong oxidising agents

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO_2)
- metallic oxide smokes
- formaldehyde vapors
- halogenic compounds

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

a) Acute toxicity :

FORMALDEHYDE 40% (CAS: 50-00-0)

Oral route :	LD50 = 243.9 mg/kg body weight
Dermal route :	LD50 = 564.85 mg/kg body weight
Inhalation route (Vapours) :	LC50 = 261 ppm

POLYOXYMETHYLENE (CAS: 30525-89-4)

Oral route :	LD50 = 592 mg/kg body weight Species : Rat
Dermal route :	LD50 > 10000 mg/kg body weight Species : Rat
Inhalation route (Dusts/mist) :	LC50 = 1070 mg/m3 Species : Rat

IODOFORME (CAS: 75-47-8)

Oral route :	LD50 = 355 mg/kg body weight Species : Rat

ZINC OXIDE (CAS: 1314-13-2)

Oral route :	LD50 > 5000 mg/kg body weight Species : Rat OECD Guideline 401 (Acute Oral Toxicity)
Dermal route :	LD50 > 2000 mg/kg body weight Species : Rat OECD Guideline 402 (Acute Dermal Toxicity)
Inhalation route (Dusts/mist) :	LC50 > 5.7 mg/l Species : Rat

b) Skin corrosion/skin irritation :

No data available.

c) Serious damage to eyes/eye irritation :

No data available.

d) Respiratory or skin sensitisation :

No data available.

e) Germ cell mutagenicity :

No data available.

f) Carcinogenicity :

No data available.

g) Reproductive toxicant :

No data available.

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard :

No data available.

11.1.2. Mixture

11.1.2.1 Information on hazard classes

a) Acute toxicity :

Oral route :	May be harmful if swallowed.
Dermal route :	No data available.
Inhalation route (Dusts/mist) :	May be harmful by inhalation.

b) Skin corrosion/skin irritation :

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.

c) Serious damage to eyes/eye irritation :

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.

d) Respiratory or skin sensitisation :

May cause an allergic reaction by skin contact.

e) Germ cell mutagenicity :

Cause for concern owing to the possibility that it may induce heritable mutations in the germ cells of humans.

f) Carcinogenicity :

Presumed human carcinogen.

g) Reproductive toxicant :

No data available.

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard :

No data available.

11.1.2.2 Other information

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

CAS 50-00-0 : IARC Group 1 : The agent is carcinogenic to humans.

11.2. Information on other hazards

SECTION 12 : ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.1.1. Substances

ZINC OXIDE (CAS: 1314-13-2)

Crustacean toxicity :	EC50 = 0.122 mg/l Factor M = 1 Species : Daphnia magna Duration of exposure : 48 h OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)
Algae toxicity :	ECr50 = 0.136 mg/l Factor M = 1 Species : Pseudokirchnerella subcapitata Duration of exposure : 72 h OECD Guideline 201 (Alga, Growth Inhibition Test)

IODOFORME (CAS: 75-47-8)

Fish toxicity :	LC50 = 2.92 mg/l Species : Pimephales promelas Duration of exposure : 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the substances.

12.2. Persistence and degradability

12.2.1. Substances

FORMALDEHYDE 40% (CAS: 50-00-0)

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

IODOFORME (CAS: 75-47-8)

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

ZINC OXIDE (CAS: 1314-13-2)

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. Endocrine disrupting properties

No data available.

12.7. 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, 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

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2023 - IMDG 2022 [41-22] - ICAO/IATA 2024 [65]).

14.1. UN number

3077

14.2. UN proper shipping name

UN3077=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(zinc oxide)

14.3. Transport hazard class(es)

- Classification :

9

14.4. Packing group

III

14.5. Environmental hazards

- Environmentally hazardous material :

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M7	III	9	90	5 kg	274 335 375 601	E1	3	-

Not subject to this regulation if Q <= 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ	Stowage Handling	Segregation
	9	-	III	5 kg	F-A. S-F	274 335 966 967 969	E1	Category A SW23	-

Not subject to this regulation if Q <= 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ

	9	-	III	956	400 kg	956	400 kg	A97 A158 A179 A197 A215	E1
	9	-	III	Y956	30 kg G	-	-	A97 A158 A179 A197 A215	E1

Not subject to this regulation if Q <= 5 l / 5 kg (IATA 4.4.4 - DS A197)

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

Marine pollutant (IMDG 3.1.2.9):(zinc oxide)

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No data available.

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. 8 (2019)

Container information:

No data available.

Particular provisions :

No data available.

Substances that deplete the ozone layer (EC Regulation No. 1005/2009, Montreal Protocol) :

The mixture does not contain any substance posing a risk to the ozone layer.

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 :

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects .
H350	May cause cancer .
H370	Causes damage to organs .
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

H411	Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.
LC50 : The concentration of a test substance resulting in 50% lethality in a given period.
EC50 : The effective concentration of substance that causes 50% of the maximum response.
ECr50 : The effective concentration of substance that causes 50% reduction in growth rate.
REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.
CMR: Carcinogenic, mutagenic or reprotoxic.
STEL : Short-term exposure limit
TWA : Time Weighted Averages
TLV : Threshold Limit Value (exposure)
AEV : Average Exposure Value.
ADR : European agreement concerning the international carriage of dangerous goods by Road.
GHS05 : Corrosion
GHS07 : Exclamation mark
GHS08 : Health hazard
GHS09 : Environment
IATA : International Air Transport Association.
IMDG : International Maritime Dangerous Goods.
ICAO : International Civil Aviation Organisation
PBT: Persistent, bioaccumulable and toxic.
RID : Regulations concerning the International carriage of Dangerous goods by rail.
vPvB : Very persistent, very bioaccumulable.