

# Safety Data Sheet

## according to Regulation (EC) No. 1907/2006 (REACH)

**Trade name :** Lunos® Prophy Powder Gentle Clean Spearmint  
**Revision date :** 28.06.2021  
**Print date :** 28.06.2021

**Version (Revision) :** 2.0.0 (1.0.1)

### SECTION 1: Identification of the substance/mixture and of the company/ undertaking

#### 1.1 Product identifier

Lunos® Prophy Powder Gentle Clean Spearmint

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

##### Relevant identified uses

Lunos® Prophy Powder Gentle Clean is designed for supragingival application on the surface of the tooth using commercial powder jet devices.

##### Products Category [PC]

PC 0 - Other

##### Uses advised against

None, if handled according to order.

##### Remark

The product is intended for professional use.

#### 1.3 Details of the supplier of the safety data sheet

##### Supplier (manufacturer/importer/only representative/downstream user/distributor)

orochemie GmbH + Co. KG

**Street :** Max-Planck-Straße 27

**Postal code/city :** 70806 Kornwestheim

**Telephone :** +49 7154 1308-0

**Telefax :** +49 7154 1308-40

**Information contact :** DÜRR DENTAL SE, Höpfigheimer Str. 17, 74321 Bietigheim-Bissingen, Germany

Tel: +49 7142 705-0, Fax: +49 7142 705-500, info@duerrdental.com

in Great Britain/Ireland:

DÜRR DENTAL [Products] UK Ltd., 14 Linnell Way - Telford Way Industrial Estate, Kettering Northants NN16 8PS, United Kingdom

Tel: +44 1536 526740, Fax.: +44 1536 526749, info@duerruk.com

#### 1.4 Emergency telephone number

INT: +49 6132 84463 (24 h/7 d)

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Although there is no labelling required for this product, we nevertheless advise observation of the safety recommendations.

##### Classification according to Regulation (EC) No 1272/2008 [CLP]

None

#### 2.2 Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

###### Precautionary statements

P280

Wear protective gloves and eye/face protection.

###### Additional information

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

#### 2.3 Other hazards

None

### SECTION 3: Composition/information on ingredients

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### 3.2 Mixtures

#### Description

Trehalose, excipients, spearmint flavouring (limonene).

#### Hazardous ingredients

I-P-MENTHA-6,8DIEN-2-ONE ; REACH No. : 01-2119962458-25 ; EC No. : 229-352-5; CAS No. : 6485-40-1

Weight fraction : < 0,1 %

Classification 1272/2008 [CLP] : Acute Tox. 4 ; H302 Skin Sens. 1B ; H317

(R)-P-MENTHA-1,8-DIENE ; REACH No. : 01-2119529223-47 ; EC No. : 227-813-5; CAS No. : 5989-27-5

Weight fraction : < 0,01 %

Classification 1272/2008 [CLP] : Flam. Liq. 3 ; H226 Asp. Tox. 1 ; H304 Skin Irrit. 2 ; H315 Skin Sens. 1 ; H317  
Aquatic Acute 1 ; H400 Aquatic Chronic 1 ; H410

#### Additional information

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

When in doubt or if symptoms are observed, get medical advice.

#### Following inhalation

Provide fresh air.

#### In case of skin contact

Wash with plenty of water. When in doubt or if symptoms are observed, get medical advice.

#### After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

#### After ingestion

When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps.

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

No information available.

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

None

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Carbon dioxide (CO<sub>2</sub>) Extinguishing powder Water spray jet Water mist The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

#### Unsuitable extinguishing media

Full water jet

### 5.2 Special hazards arising from the substance or mixture

None known.

#### Hazardous combustion products

None known.

### 5.3 Advice for firefighters

Adapt protective equipment to surrounding fire.

#### Special protective equipment for firefighters

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Adapt protective equipment to surrounding fire.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. See protective measures under point 7 and 8.

##### For non-emergency personnel

Use personal protection equipment. Avoid dust formation. See protective measures under point 7 and 8.

##### For emergency responders

###### Personal protection equipment

See protective measures under point 7 and 8.

#### 6.2 Environmental precautions

No special environmental measures are necessary.

#### 6.3 Methods and material for containment and cleaning up

##### For cleaning up

Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation.

#### 6.4 Reference to other sections

None

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Keep/Store only in original container. Please note safety instructions and directions for use on the drum.

##### Protective measures

###### Measures to prevent fire

Usual measures for fire prevention. When using do not smoke.

#### 7.2 Conditions for safe storage, including any incompatibilities

##### Requirements for storage rooms and vessels

Keep/Store only in original container. Keep container tightly closed. Keep in a cool, well-ventilated place. Do not store in temperatures below 0 °C.

##### Hints on joint storage

Store the foodstuffs separately.

#### 7.3 Specific end use(s)

None

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### DNEL-/PNEC-values

###### DNEL/DMEL

(R)-P-MENTHA-1,8-DIENE ; CAS No. : 5989-27-5

Limit value type :	DNEL worker (systemic)
Exposure route :	Inhalation
Exposure frequency :	Long-term
Limit value :	66,7 mg/m <sup>3</sup>
Limit value type :	DNEL worker (systemic)
Exposure route :	Dermal
Exposure frequency :	Long-term
Limit value :	9,5 mg/kg
Safety factor :	24 h

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### PNEC

(R)-P-MENTHA-1,8-DIENE ; CAS No. : 5989-27-5  
Limit value type : PNEC (Aquatic, freshwater)  
Exposure time : Short-term  
Limit value : 14 µg/l  
Limit value type : PNEC (Aquatic, marine water)  
Exposure time : Short-term  
Limit value : 1,4 µg/l  
Limit value type : PNEC (Sediment, freshwater)  
Exposure time : Short-term  
Limit value : 3,85 mg/kg  
Limit value type : PNEC (Sediment, marine water)  
Exposure time : Short-term  
Limit value : 0,385 mg/kg  
Limit value type : PNEC (Soil)  
Exposure time : Short-term  
Limit value : 0,763 mg/kg  
Limit value type : PNEC (Sewage treatment plant)  
Exposure time : Short-term  
Limit value : 1,8 mg/l

## 8.2 Exposure controls

### Personal protection equipment

#### Eye/face protection

Eye glasses with side protection DIN EN 166

#### Skin protection

##### Hand protection

Short-term exposure (Level 2: < 30 min): disposable gloves to EN374 category III, e.g. nitrile rubber, material thickness 0.1 mm.

Long-term exposure (Level 6: < 480 min): protective gloves to EN374 category III, e.g. nitrile rubber, material thickness 0.7 mm.

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

##### Body protection

Body protection: not required.

#### Respiratory protection

No special measures are necessary.

### General information

Keep away from food, drink and animal feedingstuffs. Wash hands before breaks and after work. Separate storage of work clothes. When using do not eat, drink, smoke, sniff.

### Other protection measures

Provide adequate ventilation.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**Appearance :** Powder

**Colour :** white

**Odour :** like Peppermint

#### Safety characteristics

**Melting point/freezing point :** ( 1013 hPa ) No data available

**Initial boiling point and boiling range :** ( 1013 hPa ) No data available

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<b>Decomposition temperature :</b>	( 1013 hPa )	No data available	
<b>Flash point :</b>		not applicable	
<b>Auto-ignition temperature :</b>		not applicable	
<b>Lower explosion limit :</b>		not applicable	
<b>Upper explosion limit :</b>		not applicable	
<b>Vapour pressure :</b>	( 50 °C )	No data available	
<b>Density :</b>	( 20 °C )	none	
<b>Bulk density :</b>	( 20 °C )	700 - 850	kg/m <sup>3</sup>
<b>Solvent separation test :</b>	( 20 °C )	not applicable	
<b>Water solubility :</b>	( 20 °C )	No data available	
<b>pH value :</b>	( 20 °C / 20 g/l )	5,3 - 6,6	
<b>log P O/W :</b>		not applicable	
<b>Flow time :</b>	( 20 °C )	not applicable	DIN-cup 4 mm
<b>Odour threshold :</b>		No data available	
<b>Maximum VOC content (EC) :</b>		0,1	Wt %
<b>Oxidising liquids :</b>	Not oxidising.		
<b>Explosive properties :</b>	No data available.		
<b>Corrosive to metals :</b>	Not corrosive to metals.		

### 9.2 Other information

None

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

None, if handled according to order.

### 10.2 Chemical stability

Stable under recommended storage and handling conditions (see section 7).

### 10.3 Possibility of hazardous reactions

None, if handled according to order.

### 10.4 Conditions to avoid

No information available.

### 10.5 Incompatible materials

No information available.

### 10.6 Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

Based on available data, the classification criteria are not met.

#### Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	> 2500 mg/kg
Method :	OECD 423
Parameter :	ATEmix calculated
Exposure route :	Oral
Effective dose :	not relevant
Parameter :	ATE ( I-P-MENTHA-6,8DIEN-2-ONE ; CAS No. : 6485-40-1 )
Exposure route :	Oral
Effective dose :	500 mg/kg

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### Practical experience/human evidence

Avoid contact with eyes.

### Acute dermal toxicity

Parameter : ATEmix calculated  
Exposure route : Dermal  
Effective dose : not relevant  
Parameter : LD50 ( (R)-P-MENTHA-1,8-DIENE ; CAS No. : 5989-27-5 )  
Exposure route : Dermal  
Species : Rabbit  
Effective dose : > 5000 mg/kg

### Acute inhalation toxicity

Parameter : ATEmix calculated  
Exposure route : Inhalation (dust/mist)  
Effective dose : not relevant

### Corrosion

Based on available data, the classification criteria are not met.

### Skin corrosion/irritation

Not an irritant.

### Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

### Skin sensitisation

Mouse: non-sensitizing. Method : ISO 10993-12.

### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity

Based on available data, the classification criteria are not met.

#### Reproductive toxicity

Based on available data, the classification criteria are not met.

### STOT-single exposure

Based on available data, the classification criteria are not met.

### STOT-repeated exposure

Based on available data, the classification criteria are not met.

### Aspiration hazard

Based on available data, the classification criteria are not met.

### 11.5 Additional information

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity

Based on available data, the classification criteria are not met.

### 12.2 Persistence and degradability

#### Biodegradation

Biodegradable.

### 12.3 Bioaccumulative potential

No information available.

### 12.4 Mobility in soil

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### Distribution

No data available

### 12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

### 12.6 Other adverse effects

No information available.

### 12.7 Additional ecotoxicological information

No ecological problems are expected when used and handled properly.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Directive 2008/98/EC (Waste Framework Directive)

##### After intended use

##### Disposal operations

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

##### Recovery operations

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

##### Waste codes/waste designations according to EWC/AVV

Concentrate/larger quantities: 18 01 07.

## SECTION 14: Transport information

### 14.1 UN number

No dangerous good in sense of these transport regulations.

### 14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

### 14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

### 14.4 Packing group

No dangerous good in sense of these transport regulations.

### 14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

### 14.6 Special precautions for user

None

### 14.7 Maritime transport in bulk according to IMO instruments

not applicable

## SECTION 15: Regulatory information

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

#### National regulations

##### Restrictions of occupation

None

### 15.2 Chemical safety assessment

For this mixture a chemical safety assessment has not been carried out.

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### SECTION 16: Other information

#### 16.1 Indication of changes

03. Hazardous ingredients

#### 16.2 Abbreviations and acronyms

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road  
ATE = Acute Toxicity Estimates  
CAS = Chemical Abstracts Service  
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]  
CMR = Carcinogen, Mutagen or Reproductive toxicant  
CO<sub>2</sub> = Carbon dioxide  
DMEL = Derived Minimal Effect Level  
DNEL = Derived No Effect Level  
EC = European Commission  
EC50 = Half maximal effective concentration  
EN = European Standard (Norm)  
EU = European Union  
EUH statement = CLP-specific Hazard statement  
EWC = European Waste Catalogue  
GHS = Globally Harmonized System of Classification and Labelling of Chemicals  
H statement = GHS Hazard statement  
IATA = International Air Transport Association ICAO-TI = International Civil Aviation Organization-Technical Instructions  
IMDG = International Maritime Dangerous Goods  
LC50 = Median lethal concentration  
LD50 = Median lethal dose  
LogPow = Logarithm of the octanol/water partition coefficient  
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)  
NOEC/NOEL = No observed effect concentration/level  
OECD = Organisation for Economic Co-operation and Development  
PBT = Persistent, Bioaccumulative and Toxic  
PNEC = Predicted No Effect Concentration  
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation [Regulation (EC) No. 1907/2006]  
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail  
RMM = Risk Management Measure  
RRN = REACH Registration Number  
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure  
STOT-SE = Specific Target Organ Toxicity - Single Exposure  
SVHC = Substances of Very High Concern  
TLV/STEL = Threshold limit value/short-term exposure limit  
TLV/TWA = Threshold limit value/time weighted average  
UN = United Nations  
VOC = Volatile Organic Compound  
vPvB = Very Persistent and Very Bioaccumulative

#### 16.3 Key literature references and sources for data

None

#### 16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

#### 16.5 Relevant H- and EUH-phrases (Number and full text)

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.



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H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

### 16.6 Training advice

None

### 16.7 Additional information

Notice the directions for use on the label.

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The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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