

Safety Data Sheet

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

Trade name : Lunos® Prophy Powder Gentle Clean Wild Berry
Revision date : 28.06.2021
Print date : 28.06.2021

Version (Revision) : 2.0.0 (1.0.0)

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

1.1 Product identifier

Lunos® Prophy Powder Gentle Clean Wild Berry

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, berry flavouring (limonene).

Hazardous ingredients

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

Weight fraction : < 0,05 %

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 (CO₂) 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

Adapt protective equipment to surrounding fire.

SECTION 6: Accidental release measures

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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/m³

Limit value type : DNEL worker (systemic)

Exposure route : Dermal

Exposure frequency : Long-term

Limit value : 9,5 mg/kg

Safety factor : 24 h

PNEC

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

Limit value type : PNEC (Aquatic, freshwater)

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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 : fruity

Safety characteristics

Melting point/freezing point : (1013 hPa) not determined

Initial boiling point and boiling range : (1013 hPa) not relevant

Decomposition temperature : (1013 hPa) not applicable

Flash point : not applicable

Auto-ignition temperature : not applicable

Lower explosion limit : not applicable

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Upper explosion limit :		not applicable	
Vapour pressure :	(50 °C)	not determined	
Density :	(20 °C)	none	
Bulk density :	(20 °C)	700 - 850	kg/m ³
Solvent separation test :	(20 °C)	not applicable	
Water solubility :	(20 °C)	not determined	
pH :	(20 °C / 20 g/l)	5,3 - 6,6	
log P O/W :		not determined	
Flow time :	(20 °C)	not applicable	DIN-cup 4 mm
Odour threshold :		not determined	
Maximum VOC content (EC) :		0,4	Wt %
Oxidising solids :	Not oxidising.		
Explosive properties :	Not determined.		
Corrosive to metals :	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
Parameter :	ATEmix calculated
Exposure route :	Oral
Effective dose :	not relevant

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

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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

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.

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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.

SECTION 16: Other information

16.1 Indication of changes

02. Label elements

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]

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CMR = Carcinogen, Mutagen or Reproductive toxicant
CO₂ = 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.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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.

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

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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.
