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

**Trade name :** Lunos® Prophylaxis powder Gentle Clean Spearmint

**Revision:** 01.01.2018 **Version (Revision):** 1.0.1 (1.0.0)

**Print date:** 01.01.2018

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

#### 1.1 Product identifier

Lunos® Prophylaxis powder Gentle Clean Spearmint

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

"Prophylaxis Powder Gentle Clean" is designed for supragingival application on the surface of the tooth using commercial powder jet devices.

## **Product Categories [PC]**

PC0 - 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: <u>+44 1536 526740</u>, Fax.: <u>+44 1536 526749</u>, <u>info@duerruk.com</u>

## 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.

## 2.3 Other hazards

None

# **SECTION 3: Composition / information on ingredients**

## 3.2 Mixtures

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#### Description

Trehalose, excipients, spearmint flavouring (limonene).

#### **Hazardous ingredients**

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

Weight fraction: < 0,1 %

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

#### **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**

No special measures are necessary.

#### 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 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**

# 6.1 Personal precautions, protective equipment and emergency procedures

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

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#### For non-emergency personnel

Use personal protection equipment. Avoid generation of dust. 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 generation of dust.

#### 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  $5\,^{\circ}$ 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/DMEL and PNEC values**

There are no data available on the preparation itself.

# 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

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No special measures are necessary.

## General health and safety measures

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.

kg/m<sup>3</sup>

DIN-cup 4 mm

#### Occupational exposure controls

#### Technical measures to prevent exposure

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 relevant basis data

Melting point/melting range: (1013 hPa) No data available Initial boiling point and boiling (1013 hPa) No data available range:

**Decomposition temperature:** (1013 hPa) No data available Flash point: not applicable Ignition temperature: not applicable Lower explosion limit: not applicable Upper explosion limit: not applicable Vapour pressure : (50°C) No data available Density: (20°C) none **Bulk density:** (20°C) 700 - 850

Solvent separation test : (20°C) not applicable Water solubility: (20°C) No data available 6,2 - 6,4 pH value: ( 20 °C / 20 g/l ) log P O/W: not applicable

Flow time: (20°C) not applicable No data available Odour threshold:

Maximum VOC content (EC): 0,1 Wt %

Oxidising liquids: Not oxidizing. **Explosive properties:** No data available. 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.

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## 10.6 Hazardous decomposition products

None known.

## **SECTION 11: Toxicological information**

## 11.1 Information on toxicological effects

#### **Acute effects**

# **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

Practical experience/human evidence

# Avoid contact with eyes. Acute dermal toxicity

Parameter: ATEmix calculated

Exposure route : Dermal

Effective dose : not relevant

## Acute inhalation toxicity

Parameter: ATEmix calculated
Exposure route: Inhalative (vapour)
Effective dose: not relevant

#### **Irritant and corrosive effects**

#### Primary irritation to the skin

Parameter: Primary irritation to the skin

Species: Rabbit
Parameter: Kaninchen
Effective dose: 0
Method: OECD 404

Not an irritant.

# Sensitisation

## In case of skin contact

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

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

No information available.

#### 11.5 Additional information

The classification was carried out according to the calculation method of Regulation No. (EC) 1272/2008 [CLP] as well as in-house investigations.

# **SECTION 12: Ecological information**

## 12.1 Toxicity

## **Aquatic toxicity**

There are no data available on the preparation itself.

# 12.2 Persistence and degradability

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No information available.

#### 12.3 Bioaccumulative potential

No information available.

#### 12.4 Mobility in soil

## Known or predicted distribution to environmental compartments

No data available

#### Adsorption/Desorption

# 12.5 Results of PBT and vPvB assessment

No information available.

#### 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

# **Product/Packaging disposal**

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

#### Waste code product

Concentrate/larger quantities: 18 01 07.

#### **Waste treatment options**

#### Appropriate disposal / Product

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

#### Appropriate disposal / Package

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

# **SECTION 14: Transport information**

## 14.1 UN number

No dangerous goods in sense of this transport regulation.

## 14.2 UN proper shipping name

No dangerous goods in sense of this transport regulation.

## 14.3 Transport hazard class(es)

No dangerous goods in sense of this transport regulation.

#### 14.4 Packing group

No dangerous goods in sense of this transport regulation.

## 14.5 Environmental hazards

No dangerous goods in sense of this transport regulation.

#### 14.6 Special precautions for user

None

# 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not applicable

## **SECTION 15: Regulatory information**

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

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# 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

# 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

 $CO_2$  = 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

 ${\sf STOT\text{-}RE} = {\sf Specific} \; {\sf Target} \; {\sf Organ} \; {\sf Toxicity} \; {\sf -} \; {\sf Repeated} \; {\sf Exposure}$ 

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

# Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

No information available.

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

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction.

## 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 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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