

Safety Data Sheet

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

Trade name : Lunos® Fluoridgel
Revision : 01.01.2018
Print date : 01.01.2018

Version (Revision): 1.0.1 (1.0.0)

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

1.1 Product identifier

Lunos® Fluoridgel

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

Relevant identified uses

Lunos® Fluoride Gel is used for caries prophylaxis with sodium fluoride and for remineralisation.

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

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Information contact : DÜRR DENTAL SE, Höpfigheimer Str. 17, 74321 Bietigheim-Bissingen, Germany
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in Great Britain/Ireland:

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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.

Special rules for supplemental label elements for certain mixtures

EUH208 Contains 3-P-MENTHANONE. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

Special rules for labelling of plant protection products

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

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Special danger of slipping by leaking/spilling product.

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Description

10 g Fluoride Gel contains 0.272 g NaF.

Hazardous ingredients

SODIUM FLUORIDE ; REACH registration No. : - ; EC No. : 231-667-8; CAS No. : 7681-49-4

Weight fraction : $\geq 1 - < 5 \%$

Classification 1272/2008 [CLP] : Acute Tox. 3 ; H301 Skin Irrit. 2 ; H315 Eye Irrit. 2 ; H319

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. Do not leave affected person unattended. Remove victim out of the danger area. Put victim at rest, cover with a blanket and keep warm. Remove contaminated, saturated clothing immediately. If unconscious place in recovery position and seek medical advice. Never give anything by mouth to an unconscious person or a person with cramps.

Following inhalation

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

In case of skin contact

After contact with skin, wash immediately with plenty of water and soap. When in doubt or if symptoms are observed, get medical advice.

After eye contact

Remove contact lenses, keep eyelids open. 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

Rinse mouth thoroughly with water. No special measures are necessary. Never give anything by mouth to an unconscious person or a person with cramps. When in doubt or if symptoms are observed, get medical advice.

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

Nitrogen oxides (NO_x)

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5.3 Advice for firefighters

Adapt protective equipment to surrounding fire. Do not inhale explosion and combustion gases. Co-ordinate fire-fighting measures to the fire surroundings. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Fight fire with normal precautions from a reasonable distance.

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.

For non-emergency personnel

Remove persons to safety. Use personal protection equipment. See protective measures under point 7 and 8.

For emergency responders

In case of fire: Wear self-contained breathing apparatus.

Personal protection equipment

See protective measures under point 7 and 8.

6.2 Environmental precautions

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

6.3 Methods and material for containment and cleaning up

For containment

Cover drains.

For cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

Other information

Collect in closed and suitable containers for disposal. Ventilate affected area.

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.

Measures to prevent aerosol and dust generation

Provide adequate ventilation.

Advices on general occupational hygiene

Wash hands thoroughly after handling. When using do not eat, drink, smoke, sniff.

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 at temperatures below 0 °C. Do not store at temperatures above 28 °C.

Hints on joint storage

Store the foodstuffs separately.

Further information on storage conditions

Protect against : Frost

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7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

SODIUM FLUORIDE ; CAS No. : 7681-49-4

Limit value type (country of origin) : TWA (EC)

Limit value : 2,5 mg/m³

Version : 08.06.2000

DNEL/DMEL and PNEC values

There are no data available on the preparation itself.

DNEL/DMEL

Limit value type : DNEL worker (local) (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Inhalation

Exposure frequency : Long-term

Limit value : 2,5 mg/m³

Limit value type : DNEL worker (local and systemic) (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Inhalation

Exposure frequency : Short-term (acute)

Limit value : 2,5 mg/m³

Limit value type : DNEL worker (systemic) (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Dermal

Exposure frequency : Long-term

Limit value : 0,36 mg/kg

Safety factor : 24 h

Limit value type : DNEL worker (systemic) (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Dermal

Exposure frequency : Short-term (acute)

Limit value : 0,36 mg/kg

Safety factor : 24 h

PNEC

Limit value type : PNEC aquatic, freshwater (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Water (Including sewage plant)

Exposure time : Short-term (single)

Limit value : 0,9 mg/l

Limit value type : PNEC (Industrial) (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Soil

Exposure time : Short-term (single)

Limit value : 11 mg/kg

Limit value type : PNEC sewage treatment plant (STP) (SODIUM FLUORIDE ; CAS No. : 7681-49-4)

Exposure route : Water (Including sewage plant)

Exposure time : Short-term (single)

Limit value : 51 mg/l

8.2 Exposure controls

Appropriate engineering controls

Provide adequate ventilation.

Personal protection equipment

Eye/face protection

No special measures are necessary.

Suitable eye protection

Eye glasses with side protection

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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.

Other protection measures

Take recovery periods for skin regeneration. Wash hands before breaks and after work.

Respiratory protection

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.

Occupational exposure controls

Use appropriate container to avoid environmental contamination. Do not allow to enter into surface water or drains.

Technical measures to prevent exposure

Provide adequate ventilation.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Gel

Colour : cloudy

Odour : fruity

Safety relevant basis data

Melting point/melting range :	(1013 hPa)			not determined
Initial boiling point and boiling range :	(1013 hPa)			not determined
Decomposition temperature :	(1013 hPa)			not determined
Flash point :				not determined
Ignition temperature :				not determined
Lower explosion limit :				not determined
Upper explosion limit :				not determined
Vapour pressure :	(50 °C)			not determined
Density :	(20 °C)			1 - 1,2 g/cm ³
Solvent separation test :	(20 °C)	<		3 %
Water solubility :	(20 °C)			not determined
pH :				5 - 6
log P O/W :				No data available
Flow time :	(20 °C)	>		12 s
Viscosity :	(20 °C)			not determined
Odour threshold :				not determined
Vapourisation rate :				not determined
Maximum VOC content (EC) :				0,3 Wt %
Explosive properties :				Not applicable.
Corrosive to metals :				No data available.

9.2 Other information

None

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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 effects

Acute oral toxicity

Parameter :	ATEmix calculated
Exposure route :	Oral
Effective dose :	3663 mg/kg
Parameter :	LD50 (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Exposure route :	Oral
Species :	Rat
Effective dose :	52 mg/kg
Parameter :	LD50 (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Exposure route :	Oral
Species :	Rat
Effective dose :	31 mg/kg
Parameter :	LD50 (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Exposure route :	Oral
Species :	Mouse
Effective dose :	44 mg/kg
Parameter :	ATE (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Exposure route :	Oral
Effective dose :	100 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

Not an irritant.

Irritation to eyes

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Not an irritant.

Sensitisation

May produce an allergic reaction.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

No information available.

Aspiration hazard

No information available.

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

There are no data available on the preparation itself.

Acute (short-term) fish toxicity

Parameter : LC50 (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Species : Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 200 mg/l
Exposure time : 96 h

Chronic (long-term) fish toxicity

Parameter : NOEC (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Species : Fish
Evaluation parameter : Chronic (long-term) fish toxicity
Effective dose : 500 mg/l
Exposure time : 96 h

Acute (short-term) daphnia toxicity

Parameter : EC50 (SODIUM FLUORIDE ; CAS No. : 7681-49-4)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 98 mg/l
Exposure time : 48 h

12.2 Persistence and degradability

Biodegradation

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 information available.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Do not allow to enter into surface water or drains. Avoid release to the environment. Refer to special instructions/Safety data sheets.

Product/Packaging disposal

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

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

EU legislation

Other regulations (EU)

Regulation (EC) No. 648/2004 (Detergents regulation)

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

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16.2 Abbreviations and acronyms

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimates

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CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
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) 1272/2008 [CLP]

No information available.

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

H301	Toxic if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

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.
