

Material Safety Data Sheet
according to regulation (EC) No. 1907/2006



Trade name: Straumann® Emdogain
Revision date: 07/08/2013 **Version:** 2.0
Print date: 07/08/2013

01. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Straumann® Emdogain

REACH-Registration No.

Not available.

Use of the substance/preparation

Straumann® Emdogain is intended as an adjunct to periodontal surgery as a topical application onto exposed root surfaces.

Manufacturer/Distributor

Institut Straumann AG

Street/P.O. Box

Peter Merian-Weg 12
CH- 4052 Basel

Country/Postal code/City

CH-4052 Basel

Technical information contact

info@straumann.com

Telephone / telefax / e-mail

+41 61 965 11 11 / +41 61 965 11 01 / info@straumann.com

Emergency telephone

+41 44 251 51 51

Swiss Toxicological Information Centre

02. Hazards identification

Hazards description

None

Classification according to directive 1272/2008/EC, 67/548/ECC or 1999/45/EC:

The preparation is subject to directive 93/42/EEC (Medical Device Directive).

The preparation is not classified according to directive 1272/2008/EC, 67/548/EEC or directive 1999/45/EC.

Informations pertaining to special dangers for human and environment:

May cause protein allergy.

03. Composition/Information on ingredients

Chemical characterization (preparation)

Viscous protein emulsion (may be in two phases)

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Ingredients:

Component	Substance name	EC-No.	CAS-No.	Index-No.	Concentration	Classification according directive 1272/2008	
						Hazard note	R-phrases
1	Protein (porcine amelogenin)	n.a.	n.a.	n.a.	27-36 mg/ml	none	none
2	Propylene Glycol Alginate	n.a.	9005-37-2	n.a.	6-8% w/w	none	none
3	Acetic acid/acetate	200-580-7	64-19-7	n.a.	< 1% w/w	none	none
4	Salts, mostly calcium	n.a.	n.a.	n.a.	< 0.2 mg/ml	none	none
5	Water	231-791-2	7732-18-5	n.a.	> 85% w/w	none	none

* n.a.= not available

Remark: Classification according to directive (EC) Nr. 1272/2008 not necessary

Full text of any risk phrases: see under section 16.

04. First aid measures

General information

May cause protein allergy. Avoid eye contact.

In case of inhalation

None.

Recommendation: Supply fresh air.

In case of skin contact

None.

Recommendation: After contact with skin, wash with soap and plenty of water.

In case of eye contact

Rinse immediately carefully and thoroughly with eye-bath or water.

In case of eye irritation consult an ophthalmologist.

In case of ingestion

None.

Recommendation: Rinse mouth thoroughly with water.

Information to physician

None.

05. Fire-fighting measures

Suitable extinguishing media

Use water, sand, dry extinguishing powder or foam.

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Extinguishing media which must not be used for safety reasons

Full water jet.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

In case of fire may be liberated:

Carbon oxides (CO_x)

Nitrogen oxides (NO_x)

Sulphur oxides

Special protective equipment for fire-fighters

Use suitable personal protective equipment. Clean all equipment after use. Use self-containing breathing apparatus.

Additional information

The preparation is not flammable.

Remark: Measures for the packaging.

06. Accidental release measures

Personal precautions

None.

Environmental precautions

None.

Methods for cleaning up

Wipe up with absorbent material (e.g. cloth, fleece).

Clear contaminated areas thoroughly.

Additional information

None.

07. Handling and storage

Advices on safe handling

Use only for intended purpose in dentistry.

Please note the handling of needles.

Precautions against fire and explosion

None.

Further information

None.

Technical measures and storage conditions

Straumann® Emdogain should be stored in a refrigerator at a storage temperature of 2 °C up to 8°C

Requirements for storage rooms and vessels

Keep/store only in original container in refrigerator.

Storage class: Not available.

Specific uses

Only for intended use in dentistry.

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08. Exposure controls / personal protection

Components with occupational exposure limits resp. biological occupational exposure limits requiring monitoring:

None.

Exposure controls

Does not contain substances in concentrations above regulated value limits, which recommend exposure controls.

Personal protection equipment

Not necessary.

Respiratory protection

Not necessary.

Recommendation: Provide adequate ventilation.

Hand protection

Not necessary.

Recommendation: Use gloves if skin contact is possible.

Eye protection

Not necessary.

Recommendation: Safety glasses with side protection.

Protective clothing

Not necessary.

Recommendation: according working environment

Organisational measures to prevent exposure

Observe profession specific hygienic measures.

Environmental exposure controls

Observe general environmental protection measures.

09. Physical and chemical properties

Information refers to the end product.

Appearance

Physical state: Viscous emulsion (may be in two phases)

Colour: Light yellow to light brown

Odour: none

Safety relevant basic data

Explosion limits:

lower: not available

upper: not available

Vapour pressure: not available

Density: 1 g/ml

Viscosity, dynamic: > 1.5 Pa s

Water solubility: Soluble in cold water

pH-Value: 4-5

Boiling point/-range: not available

Flash point: not available

Ignition temperature: not available

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10. Stability and reactivity

Stable under recommended storage conditions for 24 months after manufacturing date. (see section 7)
The preparation is not reactive with typical substances in the designated area of application.

Conditions to avoid

None.

Materials to avoid

None.

Recommendation: Do not mix with acids and oxidizing agents.

Hazardous decomposition products

None.

No hazardous decomposition products are formed.

11. Toxicological information

Toxicological assessment

The Safety of Straumann® Emdogain has been documented through a number of thorough toxicology programs, which resulted in approval of the U.S. Food and Drug Administration. Based on clinical trials there are indications that the immunogenic potential (by serum analysis) of Straumann® Emdogain is extremely low when applied in conjunction with periodontal surgery.

(Source: Zetterström O., et al. . 1997. Clinical safety of enamel matrix derivative (EMDOGAIN) in the treatment of periodontal defects. Journal of Clinical Periodontology. Volume 24 Issue 9, Pages 697 – 704)

Experiences made in practice

Ingestion is not hazardous to health. The protein decomposes to amino acids. The propylene glycol alginate decomposes to propylene glycol and alginic acid which are generally regarded as safe (GRAS).

Eye contact with the acidic Gel may cause smart.

Ingredient remarks

Propylene Glycol Alginate:

LD₅₀ oral rat: 7200 mg/kg
LD₅₀ oral mouse: 7800 mg/kg
LD₅₀ oral rabbit: 7600 mg/kg
LD₅₀ oral hamster: 7000 mg/kg

Reference: Food & Drug Research Laboratories, Inc., Papers. Vol. 124, 1976.

12. Ecological information

Ecotoxicity

No data available for the product. Contains no substances classified as hazardous to the environment. This product is not expected to have significant environmental effects. No significant effects on aquatic organisms are expected.

Mobility

No data available for the product.

Persistence and degradability

No data available for the product. This product is expected to be rapidly decomposed in nature.

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Bio accumulative potential

No data available for the product. This product is not expected to have a significant bio accumulative potential.

Results of PBT assessment

Not available.

Other adverse effects

Unknown.

13. Disposal considerations

Preparation

Straumann® Emdogain – unused / remained preparation and packaging

Dispose of waste according to applicable local, state and federal regulations.

Recommendation

The allocation of the waste codes should be in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

Waste codes according to Abfallverzeichnis-Verordnung (D) (AVV, date 15th July 2006)

Conventional waste.

Recommendation:

Used syringes and needles:

18 01 01 - Sharps (except 18 01 03)

Appropriate packaging

Dispose of waste according to applicable local, state and federal regulations.

Conventional waste

Recommendation:

15 01 06 - Mixed packaging.

14. Transport information

Land transport ADR/RID/ADN/GGVSEB

Transport of this material is not restricted, not a dangerous good.

Sea transport IMDG/GGVSee

Transport of this material is not restricted, not a dangerous good.

Air transport ICAO-TI und IATA-DGR

Transport of this material is not restricted, not a dangerous good.

15. Regulatory information

Chemical safety assessment

For this preparation a chemical safety assessment is not required.

Labelling according to directive (EC) No. 67/548/EEC or No. 1999/45/EC:

The Product does not require labelling according to the directives mentioned above.

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Labelling according to directive (EC) No. 1272/2008:

The Product does not require labelling according to the directives mentioned above.

EU-Regulations

The Product is regulated according to the medical device directive 93/42/EEC.

National regulations (D)

The Product is regulated according to the German Medizinproduktegesetz (MPG) (Date 07/2009).

Water hazard class

Class: Not available.

16. Other information

Related EU-directives

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Manufacturer's suggested restrictions on use

Indications for use:

Straumann® Emdogain is intended as an adjunct to periodontal surgery as a topical application onto exposed root surfaces.

Straumann® Emdogain is indicated for the treatment of the following conditions:

- Intrabony defects due to moderate or severe periodontitis
- Mandibular degree II furcations with minimal interproximal bone loss
- Coronally Advance Flap for treatment of gingival recession defects
- Minimally invasive surgery technique in esthetic.

Contraindications:

Straumann® Emdogain should not be used in patients with disorders or conditions including, but not limited to the following: uncontrolled diabetes or other uncontrolled systemic diseases, disorders or treatments that compromise wound healing, chronic high dose steroid therapy, bone metabolic diseases, radiation or other immuno-oppressive therapy and infections or vascular impairment at the surgical site.

R-Phrases referred to in chapter 2 and 3

None.

Additional hints

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Safety advices (S-phrases)

- | | |
|---------|---|
| S1/2 | <i>Keep locked up and out of the reach of children.</i> |
| S3/9/49 | <i>Keep only in the original container in a cool, well-ventilated place.</i> |
| S25 | <i>Avoid contact with eyes.</i> |
| S28.2 | <i>After contact with skin, wash immediately with plenty of water and soap.</i> |
| S35 | <i>This material and its container must be disposed of in a safe way.</i> |
| S43 | <i>For extinguishing, use sand, powder or foam.</i> |
| S50 | <i>Do not mix with acids and oxidizing agents.</i> |

Version changes

- 1.0 Recreation and update of the manufacturers (Biora AB, Medeon Science Park, SE-205 12 Malmö, Sweden) Material Safety Data Sheet.
- 2.0 Change request 13619 – contents unchanged

Supplier of safety data sheet

Product Safety Officer, Institut Straumann AG

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Manufacturer/Distributor notes

The statements in this MSDS are based on our present knowledge and are intended to describe the product from a safety point of view. The sheet shall therefore not be considered as a specification. The information in this sheet is accurate according to Institut Straumanns AG knowledge and has been given in good faith. It is, however, the responsibility of the customer to check that the product is used for its specific purpose and that the information in this sheet is followed. Institut Straumann AG is not responsible for damages incurred by the use of the product described, if furnished information is disregarded. It is therefore the responsibility of the customer to check if the information is sufficient for the purpose for which the product will be used.
