

SAFETY DATA SHEET

In accordance with 1907/2006/EC Article 31 and 1272/2008

(All references to EU regulations and directives are abbreviated into only the numeric term)

Issued 2017-04-24; Version number 2.0

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

1.1. Product identifier

Trade name:

Tuf-Link II

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

Identified uses: Medical device, denture relining material

1.3. Details of the supplier of the safety data sheet

Company: Dentatus AB
Finspångsgatan 42
SE-163 53 Spånga
Sweden

Telephone: 08-54650900

E-mail: info@dentatus.se

1.4. Emergency telephone number

Acute cases: Call 112, request poison information. Less acute cases: Call 111 (England, Wales and Scotland).

In the USA: Call 800-222-1222, <http://www.aapcc.org/>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This article is not classified as being hazardous as assessed in accordance to 1272/2008.

2.2. Label elements

Hazard pictogram Not applicable

Signal word Not applicable

Hazard statement Not applicable

2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
Polydimethyl-polymethyl-vinyl-siloxane, Polydimethyl-polymethyl-hydrogen-siloxane, silica	none	

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in Normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

SECTION 4: First aid measures

4.1. Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

For safety reasons, flush eyes with water; If symptoms persist, seek medical advice.

SAFETY DATA SHEET

Upon skin contact

Wash the skin with soap and water.

Upon ingestion

Rinse nose, mouth and throat with water.

Get medical attention if feeling unwell.

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

No further relevant information available.

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

Symptomatic treatment.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

CO₂, water

5.2. Special hazards arising from the substance or mixture

No further relevant information available..

5.3. Advice for fire-fighters

Protective measures should be taken regarding other material at the site of the fire.

In case of fire use a respirator mask.

Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No special equipment is deemed necessary.

6.2. Environmental precautions

Avoid release to drains, soil or watercourses. No special measures required.

6.3. Methods and material for containment and cleaning up

Collect mechanically.

6.4. Reference to other sections

See also section 7 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No specific action is required. For dental use only.

7.2. Conditions for safe storage, including any incompatibilities

No special storage restrictions.

7.3. Specific end uses

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limit values

All ingredients (cf. Section 3) lack occupational exposure limit values.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Not indicated.

8.2.1. Appropriate engineering controls

Handle in premises which have modern ventilation standards.

Eye/face protection

Eye protection should be worn if there is any danger of direct exposure or splashing.

Skin protection

Follow current local regulations for recommending protective gloves.

Respiratory protection

Respiratory protection is not normally required.

8.2.3. Environmental exposure controls

No specific measures needed.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance	Form: paste Colour: pink
b) Odour	odorless
c) Odour threshold	Not applicable
d) pH	Neutral
e) Melting point/freezing point , °C	Not indicated
f) Initial boiling point and boiling range	Not indicated
g) Flash point	Not indicated
h) Evaporation rate	Not indicated
i) Flammability (solid, gas)	Not applicable
j) Upper/lower flammability or explosive limits	Not indicated
k) Vapour pressure	Not applicable
l) Vapour density	Not applicable
m) Relative density (at 20°C, g/cm ³)	1,05
n) Solubility	Partially in toluene, petrol, ether. Not soluble in wter
o) Partition coefficient: n-octanol/water	Not applicable
p) Auto-ignition temperature	Not indicated
q) Decomposition temperature	Not indicated
r) Viscosity	Not indicated (paste)
s) Explosive properties	Not applicable
t) Oxidizing properties	Not applicable

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

10.4. Conditions to avoid

None in particular.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None under normal conditions of storage and use..

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Not indicated.

Acute toxicity

The product is not classified as harmful to health.

Skin corrosion/irritation

No skin irritation has been detected in the event of normal use.

Serious eye damage/irritation

No eye irritation has been detected in the event of normal use

Respiratory or skin sensitisation

The product does not contain any known allergens.

Germ cell mutagenicity

No mutagenic effects have been reported for the substance in this mixture.

Carcinogenicity

No carcinogenic effects have been reported for the substances in this product.

Reproductive toxicity

No toxic effects to reproduction have been reported for the substances in this mixture.

STOT-single exposure

No known hazards for occasional exposure.

STOT-repeated exposure

No known hazards for repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information**12.1. Toxicity**

No ecological damage is known or expected in the event of normal use.

Avoid larger spills in soil, water and drains.

12.2. Persistence and degradability

There is no information regarding persistence or degradability.

12.3. Bioaccumulative potential

There is no information regarding bioaccumulation.

12.4. Mobility in soil

Information about mobility in nature is not available.

12.5. Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Waste handling of the product**

The product is not classified as hazardous waste.

Small quantities can be disposed of with household waste.

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Avoid discharge into sewers.

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number

Not classified as dangerous goods

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

14.8 Other transport information

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

15.2. Chemical safety assessment

Chemical safety report according to 1907/2006 Annex I is not required for this product.

SECTION 16: Other information**16a. Indication of where changes have been made to the previous version of the safety data sheet****Revisions of this document**

Correction to company address. Design change to form.

16b. Legend to abbreviations and acronyms used in the safety data sheet

Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road
RID Regulations concerning the International Transport of Dangerous Goods by Rail
IMDG International Maritime Dangerous Goods Code
ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)
IATA The International Air Transport Association

16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet

1907/2006 Annex II (2015/830) Regulation	COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
1272/2008 THE	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
1907/2006 THE Regulation	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, and 2000/21/EC
93/105/EC	

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

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16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse

This product is not expected to cause severe harm to humans or the environment. However the manufacturer, the distributor or the supplier cannot be responsible for unusual or criminal use of the product.

Other relevant information

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Editorial information

This safety data sheet has been prepared by Dentatus AB, Finspångsgatan 42, SE-163 53 Spånga, Sweden, www.dentatus.com, based on information provided by Dr. Jürgen Engelbrecht, Tel +49 4121/483-0