

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

1 Section: Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Substance / Trade name: Fittydent Denture Adhesive Comfort Cushions

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

Relevant identified uses: Medical device Class 1 for dental prosthetics, Cushions for lower dentures

No further relevant information available

1.3 Details of the supplier of the safety data sheet

Supplier: FITTYDENT INTERNATIONAL GmbH
Address: Carlberggasse 38/Top 3/1 OG
Country code/ZIP/City: AT-1230 Vienna
Phone / Fax / E-Mail: Tel.: +43 1 381 81 81
Fax: +43 1 381 81 82
E-Mail: office@fittydent.com

1.4 EMERGENCY TELEPHONE NUMBER

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24h)

2 Section: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

This product does not meet the criteria for classification in accordance with the above regulation

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP/GHS) pictogram:

No labelling required in accordance with the above Regulation

Signal word: not applicable
Labelling according to hazardous component contains: not applicable
Hazard statements: none
Precautionary statements: none
Supplemental Hazard information: none

2.3 Other hazards

PBT and vPvB not applicable

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

3 Section: Composition/information on ingredients

3.1 Substances

This product is a mixture

Adhesive cushion, coated with a formulation based on polyvinylacetate; thickener carboxymethylcellulose

CAS Nr.	Substance name	concentration % w/w
25609-89-6	Polyvinylacetate	15 to 40
9004-32-4	Sodium Carboxymethylcellulose	30 to 70
102-76-1	Triacetine	5 to 20
Description: white mineral oil	paraffinum liquidum Ph. Eur.	5 to 20

4 Section: First aid measures

4.1 Description of first aid measures

General information: Remove contaminated clothes immediately in case of discomfort seek medical advice

Following skin contact

Wash with plenty of water and soap

Following eye contact

Remove contact lenses, rinse immediately with plenty of water, keep lid gap open; if necessary, consult an eye specialist

Following ingestion

Immediately rinse mouth thoroughly, sip plenty of water (dilution effect). Do not vomit, do not apply neutralizing agents.

4.2 Most important symptoms and effects, both acute and delayed

No additional information available

4.3 Indication of any immediate medical attention and special treatment needed

None

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

5 Section: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: water spray jet, foam, carbon dioxide, extinguishing powder, atomized spray (water)

Unsuitable extinguishing media: Do not apply water full jet in order to avoid further proliferation of the fire

5.2 Special hazards arising from the substance or mixture

In case of fire hazardous combustion products like carbon monoxide and carbon dioxide may be formed.

5.3 Advice for fire-fighters

Wear suitable protective equipment and use self-contained breathing apparatus inside the hazard area.

Arising vapors may be precipitated with water.

Avoid intrusion of firefighting water into surface water, ground water and soil.

6 Section: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Adequate ventilation of the affected area

Do not inhale gases/aerosols

Wear protective equipment

For emergency responders

Wear protective equipment according to section 8

6.2 Environmental precautions

Avoid intrusion of firefighting water into surface water, ground water and soil, cover sewer inlets.

6.3 Methods and material for containment and cleaning up

Collect scrap and contaminated material in suitable containers, care for proper disposal according to local regulations.

6.4 Reference to other sections

For protective measures see also sections 7, 8 and 13.

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

7 Section: Handling and storage

7.1 Precautions for safe handling

Store in tightly closed containers in ventilated and dry storage room.

Fire preventions

Take care of proper ventilation
Keep away from ignition sources
Take measures against electrostatically charge

Aerosol and dust generation precautions

Not to be expected, if handled and processed appropriate

Environmental precautions

Use dry storage room with impermeable flooring

Advice on general occupational hygiene

Do not eat, drink or smoke in working areas
After skin contact wash with water and soap.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Recommended storage temperature: room temperature
Do not store together with substances liable to spontaneous combustion or substances, which form flammable gases or with organic peroxides.

Requirements for storage rooms and vessels

Store in ventilated and dry rooms with impermeable flooring, keep vessels tightly closed.

Storage class: none

Specific and uses: See product folder or www.fittydent.com

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

8 Section: Exposure controls / personal protection

8.1 Control parameters

none

8.2 Occupational exposure limits

none

8.3 Exposure controls

none

Appropriate engineering controls

Take care of appropriate ventilation.

Personal protective equipment Eye/ Face protection

Use of Safety goggles with protective side shields according to EN 166 2001

Skin protection Gloves

Nitrile rubber, thickness of the glove material min. 0,7 mm

Environmental exposure controls

See sections 6 and 7

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

9 Section: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	
- Physical state:	solid
- Colour:	white
Odor:	specific
Odor threshold:	no data available
pH:	not applicable
Melting point/freezing point:	not determined
Initial boiling point/boiling range:	not applicable
Flash point:	not applicable
Evaporation rate:	not applicable
Flammability (solid, gas):	not determined
Upper/lower explosive limits:	not applicable
Vapor pressure:	not applicable
Vapor density:	not applicable
Relative density:	not applicable
Solubility(ies):	not determined
Partition Coefficient: n-octanol/water:	not applicable
Auto-ignition temperature:	not applicable
Decomposition temperature:	not determined
Viscosity:	not applicable
Explosive properties:	not applicable
Oxidizing properties:	not applicable

9.2 Other information

No additional information available

10 Section: Stability and reactivity

10.1 Reactivity

This product is under normal environmental conditions not reactive.

10.2 Chemical stability

This product is chemically stable under normal environmental conditions.

10.3 Possibility of hazardous reactions

Reaction and heat build-up with strong oxidizing agents and strong acids.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, open flames and other ignition sources.

10.5 Incompatible materials

Strong Oxidants

10.6 Hazardous decomposition products

There are no hazardous decomposition products to be expected, in case of fire hazardous combustion products may be formed. See section 5 of this safety data sheet.

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

11 Section: Toxicological information

11.1 Information on toxicological effects

Acute Toxicity

Skin corrosion/irritation:	no data available
Eye damage/irritation:	no data available
Sensitisation to the respiratory tract/skin:	no data available
CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):	no data available
Carcinogenicity:	no data available
Reproductive toxicity:	no data available
Specific target organ-toxicity (single exposure):	no data available
Specific target organ-toxicity (repeated exposure):	no data available
Aspiration hazard:	not applicable

Symptoms related to the physical, chemical and toxicological characteristics in addition:

Information about toxicokinetic, metabolism and dispersion

no data available

12 Section: Ecological information

12.1 Toxicity

no data available

12.2 Persistence and degradability

no relevant data available

12.3 Bioaccumulative potential

no relevant data available

12.4 Mobility in soil

no relevant data available

12.5 Results of PBT- and vPvB-assessment

not applicable

12.6 Other adverse effects

no relevant data available

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

13 Section: Disposal considerations

13.1 Waste treatment methods Directive 2008/98/EC (Waste Framework Directive)

Prevent intrusion in the sewer system. Dispose of product and uncleaned vessels according to local/regional/national/international regulations.

13.2 Treatment of uncleaned packaging

Uncleaned packaging has to be treated the same way as the product.

13.3 Waste code according to European waste catalogue (AVV)

180104 wastes whose collection and disposal is not subject to special requirements in order to prevent infection.
Small amounts from private households can be disposed off with municipal waste.

14 Section: Transport information

14.1 UN-No.

not applicable

14.2 UN-proper shipping name

ADR/RID

The product is not subject to classification according to Regulations ADR/RID

IMDG-Code / ICAO-TI / IATA-DGR

The product is not subject to classification according to Regulations IMDG-Code/ICAO-TI/IATA-DGR

14.3 Transport hazard class

not applicable

14.4 Packing group

not applicable

14.5 Environmental hazards

Label environmental hazard

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR:

yes / no

Marine Pollutant:

yes / no

14.6 Special precautions for users

See sections 6 to 8

14.7 Transport in bulk according to annex II of MARPOL-73/78 and IBC-Code

The product will not be transported in bulk.

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

15 Section: Regulatory information

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

Regulation (EC) No 1005/2009 (on substances that deplete the ozone layer):

not applicable

Regulation (EC) No 850/2004 (persistent organic pollutants):

not applicable

Regulation (EC) No 689/2008 (concerning the export and import of dangerous chemicals):

not applicable

Regulation (EC) No 689/2008 (concerning medical devices):

The product is classified, registered and labelled as medical device class 1 according to this regulation

Restrictions according to Title VIII of the Regulation (EC) No 1907/2006:

none

15.2 National Regulations e.g.

Water hazard classe

not applicable

Lösemittelverordnung (31. BImSchV)

not applicable

Störfallverordnung (12. BImSchV)

not applicable

Technische Anleitung Luft (TA-Luft)

not applicable

15.3 Other relevant Regulations

United States Federal Food, Drug, and Cosmetic Act

The product is classified as 510k exempt according to the above set of laws.

15.4 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date: 3.12.2020 Revision Date: 13.06.2019
Version: 1.0 E Replaces Version:

16 Section: Other information

Modifications with respect to the previous version

Abbreviations

Key literature references and sources for data

REACH Regulation (EC) No 1907/2006, last amendment Regulation (EU) 2018/675 CLP-Regulation (EC) No. 1272/2008, last amendment Regulation (EU) 29178/669

Methods according to Article 9 of the regulation (EC) No. 1272/2008 used for classification

Health and Environmental hazards: calculation method

Relevant R-, H- and EUH-phrases (number and full text)

None

Training advice

For this product no training advice has to be provided