

Dental



SAFETY DATA SHEET

Revision Date 15/08/2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product Name Gingibraid, Gingiknit, ShortCut
Synonyms Aluminium Potassium Sulfate Gingival Retraction Materials

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

Recommended Use Dental retraction material
Uses advised against No information available

1.3 Details of the supplier of the safety data sheet

Dux Dental B.V.
Zonnebaan 14
3542 EC Utrecht
The Netherlands
Tel: +31 (0)30-24 10 924
E-mail: info@dux-dental.com

1.4 Emergency telephone number

National Poisons Information Service (London Centre)
+44 20 7771 5307

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Not classified

2.2 Label elements

This product is a medical device which is regulated under Directive 2007/47/EC (the Medical Device Directive). As such it does not present a significant risk to the user or patient when used in accordance with manufacturer's instructions. A Safety Data Sheet is not required for medical devices according to Regulation No 1907/2006 (REACH, Article 2, point 6). This Safety Data Sheet is supplied as an additional service. The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

2.3 Other hazards

None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.2 Mixtures**

The product does not contain any hazardous materials with occupational exposure limits established.

Chemical nature Small cords impregnated with aqueous solution

SECTION 4: FIRST AID MEASURES**4.1 Description of first aid measures**

General advice	No hazards which require special first aid measures.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if irritation develops and persists.
Skin contact	Wash skin with soap and water. Get medical attention if irritation develops and persists.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Get medical attention immediately if symptoms occur.
Inhalation	Move to fresh air. Get medical attention immediately if symptoms occur.
Protection of first-aiders	Avoid contact with skin, eyes and clothing.

4.2 Most important symptoms and effects, both acute and delayed

Main symptoms No acute and delayed symptoms and effects are observed.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES**5.1 Extinguishing media**

Suitable extinguishing media The product itself does not burn. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons None known.

5.2 Special hazards arising from the substance or mixture

Special hazard Hazardous decomposition products formed under fire conditions: Sulphur oxides.

5.3 Advice for firefighters

Special protective equipment for fire-fighters Wear self-contained breathing apparatus and protective suit.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

No special precautions.

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal.

6.4 Reference to other sections

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

No special requirements. Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Store in original container. Keep container tightly closed in a dry and well-ventilated place. Incompatible materials: Metals.

7.3 Specific end use(s)

Exposure Scenario Not available.

Other Information Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**

Exposure limits Contains no substances with occupational exposure limit values.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2 Exposure controls

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye protection	No special protective equipment required.
Hand protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No special protective equipment required.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls No special environmental precautions required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

Physical state @20°C	solid
Appearance	Small cords of varying diameters and constructions
Colour	No information available
Odour	odourless
pH	No information available
Melting/freezing point	No information available
Boiling point/boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	Not flammable
Flammability Limits in Air	Not applicable
Vapour pressure	No information available
Vapour density	Not applicable
Relative density	No information available
Solubility	
Water solubility	No information available
Partition coefficient (n-octanol/water)	No information available
Autoignition Temperature	No information available
Decomposition temperature	No information available
Viscosity, dynamic	No information available
Explosive properties	Not explosive
Oxidising Properties	No information available

9.2 Other information

No information available

SECTION 10: STABILITY AND REACTIVITY**10.1 Reactivity**

No information available.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerisation does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Metals.

10.6 Hazardous decomposition products

Sulphur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

Ingestion

No known effect.

Skin contact

No known effect.

Inhalation

No known effect.

Skin corrosion/irritation

No known effect.

Serious eye damage/irritation

No known effect. Dust contact with the eyes can lead to mechanical irritation.

Respiratory or skin sensitisation

No known effect.

Germ cell mutagenicity

Not known to cause heritable genetic damage.

Carcinogenicity

Contains no ingredient listed as a carcinogen.

Reproductive toxicity

Not known to cause birth defects or have a deleterious effect on a developing fetus. Not known to adversely affect reproductive functions and organs.

STOT-single exposure

No known effect. Inhalation of dust can cause irritation to the respiratory system.

STOT-repeated exposure

No known effect.

Aspiration hazard

No known effect.

SECTION 12: ECOLOGICAL INFORMATION**12.1 Toxicity**

Contains no substances known to be hazardous for the environment.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Waste from residues / unused products

Dispose of in accordance with local regulations.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: TRANSPORT INFORMATION

According to. ADR, RID, ADN, IMDG, ICAO.

14.1 UN number

Not regulated.

14.2 UN proper shipping name

Not regulated.

14.3 Transport hazard class(es)

Not regulated.

14.4 Packing group

Not regulated.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

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****Restrictions on use**

None.

Other regulations

This product is a medical device which is regulated under Directive 2007/47/EC (the Medical Device Directive). As such it does not present a significant risk to the user or patient when used in accordance with manufacturer's instructions. A Safety Data Sheet is not required for medical devices according to Regulation No 1907/2006 (REACH, Article 2, point 6). This Safety Data Sheet is supplied as an additional service.

15.2 Chemical safety assessment

Not required.

SECTION 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3
Not applicable

Full text of H-Statements referred to under sections 2 and 3
Not applicable

Revision Note Format updated in compliance with European REACH and CLP regulations.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text