



# 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

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

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



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**SECTION 16: OTHER INFORMATION**

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**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