

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 28 Apr 2023

Print date: 19 Aug 2024

Version: 12



orthodontic-base

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

1.1. Product identifier

Trade name/designation:

orthodontic-base

Article No.:

11295

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

Use of the substance/mixture:

Dental stone

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

dentona AG

Feldbachacker 16

44149 Dortmund

Germany

Telephone: 0231-5556-0

Telefax: 0231-5556-30

E-mail: info@dentona.de

Website: www.dentona.com

1.4. Emergency telephone number

No data available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

Special rules for supplemental label elements for certain mixtures:

99,4 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (oral).

99,4 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

99,4 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

99,6 % percent of the mixture consists of components of unknown hazards to the aquatic environment.

2.3. Other hazards

No data available

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 7778-18-9 EC No.: 231-900-3 REACH No.: 01-2119444918-26-0129	calcium sulfate The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	46 - < 80 weight-%
CAS No.: 471-34-1 EC No.: 207-439-9	calcium carbonate The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	12 - ≤ 20 weight-%
CAS No.: 304-59-6 EC No.: 206-156-8 REACH No.: 01-2119524666-34	potassium sodium tartrate The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	0 - ≤ 0.2 weight-%

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

Dental stone is not considered toxic. Irritant effects on direct contact are limited to the mucous membranes of the eyes. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Take the affected person out of the danger zone and into the fresh air in self-protection.
Keep injured person calm and protect from hypothermia.
If breathing is irregular: give artificial respiration.
Call a doctor immediately Provide fresh air.

In case of skin contact:

Clean affected skin areas thoroughly under running water with soap.

After eye contact:

Rinse the eye for 10 minutes under running water, protecting the uninjured eye.
eyelids wide apart. Do not attempt to mechanically remove set plaster residues yourself. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion:

Rinse out mouth, spit out liquid again.
Immediately - if conscious - make the person drink plenty of liquid (water).
Call a doctor immediately. Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No information available May cause respiratory irritation. No known symptoms to date.

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

No information available Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

No data available The product itself does not burn.

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Hazardous combustion products:

No data available In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Avoid breathing dust/fume/gas/mist/vapours/spray. Remove persons to safety.

Protective equipment:

Personal protection equipment: see section 8 Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Collect spillage. Measures to prevent aerosol and dust generation Wet clean or vacuum up solids.

For cleaning up:

No information available Water (with cleaning agent)

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8). Do not breathe dust.

Measures to prevent aerosol and dust generation:

Dust should be exhausted directly at the point of origin. Additional measures for respiratory protection

High efficiency particulate air filter (HEPA filter)

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Requirements for storage rooms and vessels:

Keep/Store only in original container.

Storage class (TRGS 510, Germany): 10 - 13 - Other combustible and non-combustible substances

7.3. Specific end use(s)

No data available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
TRGS 900 (DE)	calcium sulfate CAS No.: 7778-18-9 EC No.: 231-900-3	① 6 mg/m ³ ⑤ (alveolengängige Fraktion) DFG
DFG (DE)	calcium sulfate CAS No.: 7778-18-9 EC No.: 231-900-3	① 4 mg/m ³ ⑤ (einatembare Fraktion)

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Particle filter P2 or P3, core colour white

Particle filter device (EN 143)

8.2.3. Environmental exposure controls

No information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: solid

Colour: white

Odour: sweetish

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	7	20 °C	
Melting point	No data available		
Freezing point	No data available		
Initial boiling point and boiling range	No data available		
Flash point	not applicable		
Evaporation rate	No data available		
Auto-ignition temperature	not applicable		
Vapour pressure	No data available		
Density	2.96 g/cm ³	20 °C	

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Parameter	Value	at °C	① Method ② Remark
Bulk density	No data available		
Water solubility	2.4 mg/L	20 °C	

particle characteristics:

No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Non flammable, No hazardous reaction when handled and stored according to provisions. not relevant
The product itself does not burn.

10.2. Chemical stability

Stable under recommended storage and handling conditions.

10.3. Possibility of hazardous reactions

None when used as intended

10.4. Conditions to avoid

Protect from humidity and water

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No known hazardous decomposition products. In case of fire: Gases/vapours, toxic

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

potassium sodium tartrate CAS No.: 304-59-6 EC No.: 206-156-8
LD₅₀ oral: 3,000 mg/kg (Ratte)
LD₅₀ dermal: 3,000 mg/kg (Ratte)
potassium sulfate CAS No.: 7778-80-5 EC No.: 231-915-5
LD₅₀ oral: >2,000 mg/kg (Ratte)
LD₅₀ dermal: >2,000 mg/kg (Ratte)
LC₅₀ Acute inhalation toxicity (vapour): >1.2 mg/L

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

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Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

potassium sulfate CAS No.: 7778-80-5 EC No.: 231-915-5
LC₅₀ : 680 mg/L 4 d (fish, Pimephales promelas)
EC₅₀ : 720 mg/L 2 d (crustaceans, Daphnia magna)
NOEC : >100 mg/L (Algae/water plant)

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

calcium sulfate CAS No.: 7778-18-9 EC No.: 231-900-3
Results of PBT and vPvB assessment: —
calcium carbonate CAS No.: 471-34-1 EC No.: 207-439-9
Results of PBT and vPvB assessment: —
potassium sodium tartrate CAS No.: 304-59-6 EC No.: 206-156-8
Results of PBT and vPvB assessment: —
potassium sulfate CAS No.: 7778-80-5 EC No.: 231-915-5
Results of PBT and vPvB assessment: —

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

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SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

15.1.1. EU legislation

No data available

15.1.2. National regulations

 [DE] National regulations

Water hazard class

WGK:

3 - highly hazardous to water

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
EN	European Standard
ES	Exposure scenario
HEPA	High Efficiency Particulate Air
ICAO	International Civil Aviation Organization

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IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
LC ₅₀	Lethal (fatal) Concentration 50%
LD ₅₀	Lethal (fatal) Dose 50%
MAK	Maximum concentration in the workplace air (CH)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
NOEC	No Observed Effect Concentration
OSHA	Occupational Safety & Health Administration
PBT	persistent and bioaccumulative and toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

No data available

16.6. Training advice

No data available

16.7. Additional information

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