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Visalys® BioCeramic Block
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Visalys® BioCeramic Block

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

Relevant identified uses: Medical device, for dental use only**Use of the substance/mixture**

Stone, plaster, cement, glass and ceramic articles; Aids for dental technology

1.3. Details of the supplier of the safety data sheet

Name:	Kettenbach-Dental GmbH		
Street:	Im Heerfeld 7		
Place:	D-35713 Eschenburg		
Telephone:	+49(0) 2774/705-0	Telefax:	+49(0) 2774/705-66
e-mail:	info@kettenbach.com		
Internet:	www.kettenbach.com		
Responsible Department:	R&D		

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Marking elements

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

Exempt from the requirements - products classified as medical devices or in vitro diagnostics.

Hazard pictograms not applicable**Signal word** not applicable**Hazard statements** not applicable

2.3 Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization:

Stone, plaster, cement, glass and ceramic articles

Hazardous components:

none (according to Regulation (EC) No 1907/2006 (REACH))

SECTION 4: First aid measures

4.1. Description of first aid measures

General notes:

No special measures required. Consult a doctor if symptoms persist.

After inhalation

Remove the affected person to fresh air and keep calm.

After contact with skin

Wash off immediately with water.

After contact with eyes

Rinse opened eye for several minutes under running water. Consult a doctor if symptoms persist.

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After ingestion

Rinse out mouth and drink plenty of water. Consult a doctor if symptoms persist.

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

No further relevant information available

4.3. Indications of any immediate medical help and special treatment

No further relevant information available

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

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Further information

Fire residues and contaminated extinguishing water must be disposed of in accordance with official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No special measures are necessary.

6.2. Environmental precautions measures

Do not allow to enter drains or water courses. Do not allow to enter the ground/soil.

6.3. Methods and material for containment and cleaning up

Record mechanically. Dispose of the ingested material in accordance with the regulations.

6.4. Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Protective measures for safe handling

Advice on safe handling

No special measures are necessary

Advice on protection against fire and explosion

No special fire protection measures are necessary

7.2. Conditions for safe storage, including any incompatibilities.

Requirements to be met by storerooms and receptacles:

Keep only in original unopened containers.

Information on storage together:

No special measures are necessary.

Further information on storage conditions: None.

7.3. Specific end use(s)

Stone, plaster, cement, glass and ceramic articles; Aids for dental technology

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Wash hands before breaks and at the end of work.

Hand protection

Wear suitable gloves. The selection of a suitable glove depends not only on the material but also on other quality features and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of glove materials cannot be calculated in advance and must therefore be checked before use.

Eye/face protection

Wear eye/face protection.

Respiratory protection

Avoid breathing sanding dust /swarf.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	solid
Colour:	According to product designation
Odour:	Odourless
pH value:	Not applicable

Changes in the physical status

Melting point/freezing point:	Not determined.
Initial boiling point and boiling range:	Not determined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Explosive properties:	The product is not: Explosive
Lower explosion limits:	Not determined.
Upper explosion limits:	Not determined.
Vapour pressure:	Not applicable.
Density at 20 °C:	2,2 g/cm ³
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Water solubility	Insoluble.
Partition coefficient: n-octanol/water:	Not determined.

9.2. Other information

No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions

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10.4. Conditions to avoid

None

10.5. Incompatible materials

No further relevant information available.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

Irritation and corrosivity

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

Sensitization effect

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

CMR effects (carcinogenic, mutagenic and toxic for reproduction)

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

Specific target organ toxicity at single exposure

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

Specific target organ toxicity in case of repeated exposure

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

Aspiration hazard

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

11.2. Information on other hazards

No further relevant information available.

SECTION 12: Ecological information

12.1. Toxicity

No further relevant information available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

12.5. Results of PBT and vPvB

not applicable

12.6. Endocrine disrupting properties

not applicable

12.7. Other adverse effects

No further relevant information available.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal Recommendation:

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Uncleaned packaging:

Wash with plenty of water.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN-Number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazards class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN-Number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazards class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN-Number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazards class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN-Number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazards class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards:

no

14.6. Special precautions for user:

no information available

14.7. Maritime transport in bulk according to IMO instruments:

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU
(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D):

non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessment for substances in this mixture were not carried out.

SECTION 16: Other information**Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation
intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.
(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)