

Safety Data Sheet

Kavitan PLUS/CEM (powder)

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

1.1. Product identifier

Product name : Kavitan PLUS/CEM (powder)

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

Relevant identified uses

Main use category : Professional use

Use of the substance/mixture : Preparation intended for dental medical use

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

SpofaDental a.s.
Markova 238
CZ-506 01 Jicin Czech Republic
T +420 493 583 204

Manufacturer

SpofaDental a.s.
Markova 238
CZ-506 01 Jicin Czech Republic
T +420 493 583 204

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Organisation/Company	Address	Emergency number
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Not classified

2.2. Label elements

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

Extra phrases : The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).
A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

2.3. Other hazards

Other hazards not contributing to the classification : Dust may cause painful eye irritation and tearing. Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glass, oxide, chemicals	(CAS-No.) 65997-17-3 (EC-No.) 266-046-0 (REACH-no) 01-2119488048-29	<= 100	Not classified

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general : If medical advice is needed, have product container or label at hand. Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : If swallowed, rinse mouth with water (only if the person is conscious).

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO₂) and powder.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid dust formation. Do not breathe dust.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 13. See Heading 8. Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling : Avoid dust formation. Do not breathe dust.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep cool. Keep only in original container. Keep container closed when not in use. Store in a dry place. Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal protective equipment : Gloves. Safety glasses. Avoid all unnecessary exposure.

Hand protection : Wear protective gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent). Breakthrough time : 8 (> 480 minutes). Layer thickness : 0,11 mm

Eye protection : Safety glasses. STANDARD EN 166.

Skin and body protection : Wear suitable protective clothing

Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. Dust production: dust mask with filter type P2. Standard EN 143. Standard EN 149.



Other information : Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state : Solid
 Appearance : Powder.
 Colour : white.
 Odour : odourless.
 Odour threshold : Not determined
 pH : Not determined
 Relative evaporation rate (butylacetate=1) : Not determined
 Melting point : 730 °C
 Freezing point : Not determined
 Boiling point : Not determined
 Flash point : Not determined
 Auto-ignition temperature : Not determined
 Decomposition temperature : Not determined
 Flammability (solid, gas) : Non flammable.
 Vapour pressure : Not determined
 Relative vapour density at 20 °C : Not determined
 Relative density : >= 1
 Solubility : insoluble in water.
 Log Pow : Not determined

Viscosity, kinematic : Not determined
 Viscosity, dynamic : Not determined
 Explosive properties : Product is not explosive.
 Oxidising properties : Non flammable.
 Explosive limits : Not determined

9.2. Other information

Additional information : None to our knowledge.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None to our knowledge.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity : Not classified
 Skin corrosion/irritation : Not classified
 Based on available data, the classification criteria are not met
 pH: Not determined
 Serious eye damage/irritation : Not classified
 Based on available data, the classification criteria are not met
 pH: Not determined
 Respiratory or skin sensitisation : Not classified
 Based on available data, the classification criteria are not met
 Germ cell mutagenicity : Not classified
 Based on available data, the classification criteria are not met
 Carcinogenicity : Not classified
 Based on available data, the classification criteria are not met
 Reproductive toxicity : Not classified
 Based on available data, the classification criteria are not met
 STOT-single exposure : Not classified
 Based on available data, the classification criteria are not met
 STOT-repeated exposure : Not classified
 Based on available data, the classification criteria are not met
 Aspiration hazard : Not classified
 Based on available data, the classification criteria are not met
 Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Kavitan PLUS/CEM (powder)	
Persistence and degradability	No data.

12.3. Bioaccumulative potential

Kavitan PLUS/CEM (powder)	
Log Pow	Not determined
Bioaccumulative potential	No data.

12.4. Mobility in soil

Kavitan PLUS/CEM (powder)	
Ecology - soil	No data.

12.5. Results of PBT and vPvB assessment

Kavitan PLUS/CEM (powder)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other adverse effects : None to our knowledge.
 Additional information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose of contents/container in accordance with licensed collector’s sorting instructions.
 Waste treatment methods : Dispose of contents/container in accordance with licensed collector’s sorting instructions. Do not discharge into drains.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
 Ecology - waste materials : Avoid release to the environment.
 European List of Waste (LoW) code : 18 01 07 - chemicals other than those mentioned in 18 01 06

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number	
Not regulated for transport	
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
14.4. Packing group	
14.5. Environmental hazards	
No supplementary information available	

14.6. Special precautions for user

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

EU-Regulations

Contains no REACH substances with Annex XVII restrictions
 Contains no substance on the REACH candidate list
 Contains no REACH Annex XIV substances

National regulations

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Data sources	: Classification according to Regulation (EC) No. 1272/2008 [CLP], according to Regulation (EU) 2015/830. EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.
Other information	: None.
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Version	: 1.0
Signature	: A. Åsebø Murel

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.