

## Safety Data Sheet

### Kavitan PLUS/PRO/CEM (liquid)

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

##### 1.1. Product identifier

Product name : Kavitan PLUS/PRO/CEM (liquid)

##### 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]

Skin Irrit. 2 H315

Eye Dam. 1 H318

Full text of H statements : see section 16

##### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS05

Signal word (CLP) : Danger

Hazardous ingredients	: (+)-tartaric acid
Hazard statements (CLP)	: H315 - Causes skin irritation. H318 - Causes serious eye damage.
Precautionary statements (CLP)	: P264 - Wash hands thoroughly after handling. P280 - Wear eye protection, protective gloves. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P332+P313 - If skin irritation occurs: Get medical advice/attention. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor P362+P364 - Take off contaminated clothing and wash it before reuse.
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 : None under normal conditions.

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]
Acrylic acid and itaconic acid copolymer	(CAS-No.) 25948-33-8 (REACH-no) N/A	< 100	Skin Irrit. 2, H315 Eye Irrit. 2, H319
(+)-tartaric acid	(CAS-No.) 87-69-4 (EC-No.) 201-766-0	< 10	Eye Dam. 1, H318

Full text of H-statements: see section 16

## 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.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.
First-aid measures after ingestion	: If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

## 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. Toxic fumes may be released. acrylic acid, prop-2-enoic acid.

**5.3. Advice for firefighters**

- Firefighting instructions : Use water spray or fog for cooling exposed containers.
- 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 contact with skin and eyes. Use personal protective equipment as required.

**For non-emergency personnel**

No additional information available

**For emergency responders**

No additional information available

**6.2. Environmental precautions**

Discharging into rivers and drains is forbidden.

**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 : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.

**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 : Keep container tightly closed. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

**7.2. Conditions for safe storage, including any incompatibilities**

- Storage conditions : Store in dry protected location to prevent any moisture contact. Keep container tightly closed. Keep cool. Keep only in original container.

**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.
- Hand protection : 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



- 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	: Liquid
Appearance	: Viscous.
Colour	: yellowish.
Odour	: No data available
Odour threshold	: Not determined
pH	: Not determined
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: Not determined
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	: Not determined
Solubility	: Not determined.
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**

Heat.

**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	: Causes skin irritation. pH: Not determined
Serious eye damage/irritation	: Causes serious eye damage. 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

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity**

No additional information available

**12.2. Persistence and degradability**

<b>Kavitan PLUS/PRO/CEM (liquid)</b>	
Persistence and degradability	No data.

**12.3. Bioaccumulative potential**

<b>Kavitan PLUS/PRO/CEM (liquid)</b>	
Log Pow	Not determined
Bioaccumulative potential	No data.
<b>(+)-tartaric acid (87-69-4)</b>	
Log Pow	0.24

**12.4. Mobility in soil**

<b>Kavitan PLUS/PRO/CEM (liquid)</b>	
Ecology - soil	No data.

**12.5. Results of PBT and vPvB assessment**

<b>Kavitan PLUS/PRO/CEM (liquid)</b>	
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	: No other effects known

**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	: Recover the product with absorbent material. Dispose of contents/container in accordance with licensed collector's sorting instructions. Do not discharge into drains.
Product/Packaging disposal recommendations	: Dispose of contents/container to a hazardous or special waste collection point.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 18 01 06* - chemicals consisting of or containing dangerous substances

**SECTION 14: TRANSPORT INFORMATION**

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

<b>14.1. UN number</b>	
Not regulated for transport	
<b>14.2. UN proper shipping name</b>	
<b>14.3. Transport hazard class(es)</b>	
<b>14.4. Packing group</b>	

**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 for the substance or the mixture by the supplier

**SECTION 16: OTHER INFORMATION**

Indication of changes:

2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Signal word (CLP)	Modified	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects	Removed	

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.

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Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.

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.