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Image

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PENTRON

Safety Data Sheet Image

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

1.1. Product identifier

Product name : Image

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

Relevant identified uses

Main use category : Professional use

Function or use category : Dental materials

Uses advised against

No additional information available

1.3. Details of the supplier of the safety datasheet

Supplier

SpofaDental a.s.
Markova 238
CZ-506 46 Jicin Czech Republic
T +420 493 583 204

Manufacturer

PENTRON CLINICAL
1717 West Collins Avenue
Orange, CA 92867, USA
T +1-800-5377-123
[E-mail: safety@kavokerr.com](mailto:safety@kavokerr.com)

Contact person : safety@kavokerr.com - tel. +41 91 610 06 00 (08.00-17.00)

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 +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]

Eye Dam. 1 H318

Skin Sens. 1 H317

STOT RE 2 H373

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS05



GHS07



GHS08

Signal word (CLP) : Danger

Hazardous ingredients : Kieselguhr, soda ash flux-calcined; Cristobalite; Potassium hexafluorotitanate
; Tetrasodium diphosphate

Hazard statements (CLP) : H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage

Precautionary statements (CLP)	H373 - May cause damage to organs through prolonged or repeated exposure : P260 - Do not breathe dust P280 - Wear eye protection, protective gloves 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 or doctor/physician P333+P313 - If skin irritation or rash occurs: Get medical advice/attention P362+P364 - Take off contaminated clothing and wash it before reuse P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Extra phrases	: The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1907/2006, article 2, paragraph 6c)

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. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Kieselguhr, soda ash flux-calcined	(CAS No) 68855-54-9 (EC no) 272-489-0 (REACH-no) 01-2119488518-22	30 - 60	STOT RE 2, H373
Silicon dioxide, non-respirable	(CAS No) 14464-46-1 (EC no) 238-455-4 (REACH-no) N/A	30 - 60	STOT RE 2, H373
Alginic acid, potassium salt	(CAS No) 9005-36-1 (EC no) N/A (REACH-no) N/A	10 - 30	Eye Irrit. 2, H319
Cristobalite, respirable	(CAS No) 14464-46-1 (EC no) 238-455-4 (REACH-no) N/A	1 - 5	STOT RE 2, H373
Potassium hexafluorotitanate	(CAS No) 16919-27-0 (EC no) 240-969-9 (REACH-no) 01-2119978268-20	1 - 5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335
Zinc borate	(CAS No) 138265-88-0 (EC no) – 604-070-9 (REACH-no) N/A	1 - 5	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Tetrasodium diphosphate	(CAS No) 7722-88-5 (EC no) 231-767-1 (REACH-no) 01-2119489794-17	1 - 5	Acute Tox. 4 (Oral), H302 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. 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	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell. Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Causes damage to organs.
Symptoms/injuries after inhalation	: May cause an allergic skin reaction.
Symptoms/injuries after eye contact	: Causes serious eye damage.

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 (CO ₂) 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 dioxide. Carbon monoxide.

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 contact with skin and eyes. Use personal protective equipment as required.
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For non-emergency personnel

Protective equipment	: See Heading 8.
Emergency procedures	: Evacuate unnecessary personnel.

For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Discharging into rivers and drains is forbidden. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or 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	: On land, 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	: Do not eat, drink or smoke when using this product. 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. Avoid dust formation. Avoid breathing dust.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a dry place. Store in a closed container. Store in original container. Keep container closed when not in use.
Incompatible materials	: Keep away from heat and direct sunlight.

7.3. Specific end use(s)

For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

Magnesium oxide (1309-48-4)		
United Kingdom	Local name	Magnesium oxide
United Kingdom	WEL TWA (mg/m ³)	4 mg/m ³ (as Mg) fume and respirable dust 10 mg/m ³ (as Mg) inhalable dust
Tetrasodium diphosphate (7722-88-5)		
United Kingdom	Local name	Tetrasodium pyrophosphate
United Kingdom	WEL TWA (mg/m ³)	5 mg/m ³
Calcium Sulfate Dihydrate (13397-24-5)		
United Kingdom	Local name	Gypsum
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³ inhalable dust 4 mg/m ³ respirable

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. Nitrile rubber gloves. Layer thickness : 0,09mm. Breakthrough time : >480 min. STANDARD EN 374
Eye protection	: Chemical goggles or safety glasses. STANDARD EN 166
Skin and body protection	: Wear suitable protective clothing
Respiratory protection	: In case of insufficient ventilation, wear suitable respiratory equipment. Dust production: dust mask with filter type P2. Standard EN 143



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.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Powder.
Colour	: Various.
Odour	: pleasant.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: In water, material is partially soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.

Oxidising properties : Non flammable.
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

No data available.

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

Keep away from heat and direct sunlight.

10.5. Incompatible materials

No data available.

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
Based on available data, the classification criteria are not met

Cristobalite (14464-46-1)	
LD50 oral rat	3160 mg/kg
Cristobalite (14464-46-1)	
LD50 oral rat	3160 mg/kg
Potassium hexafluorotitanate (16919-27-0)	
LD50 oral rat	324 mg/kg
Tetrasodium diphosphate (7722-88-5)	
LD50 oral rat	300 - 2000 mg/kg
LD50 oral	1825 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat (mg/l)	> 0.58

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Causes serious eye damage.

Respiratory or skin sensitisation : May cause an allergic skin reaction.

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

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : May cause damage to organs through prolonged or repeated exposure.

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**

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. Avoid discharge to the environment.
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Tetrasodium diphosphate (7722-88-5)	
LC50 fish 1	> 100 mg/l (96 h)
EC50 Daphnia 1	<= 15 ppm (72 h)

12.2. Persistence and degradability

Image	
Persistence and degradability	No data available.

12.3. Bioaccumulative potential

Image	
Bioaccumulative potential	No data.

12.4. Mobility in soil

Image	
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

Image	
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. Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Waste treatment methods**

Regional legislation (waste)	: Dispose as hazardous waste.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Waste disposal recommendations	: Dispose of contents/container to a hazardous or special waste collection point. Avoid release to the environment. 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 06* - chemicals consisting of or containing dangerous substances

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	: 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.
Date of issue	: 9/30/2016
Revision date	: 18/03/2020
Supersedes	: 9/30/2016
Date of total revision	: 9/30/2016
Version	: 2.0
Indication of changes	: Updated section 3, 11, 12

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
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
Skin Sens. 1	Sensitisation — Skin, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

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.