

according to Regulation (EU) 2020/878
 Date of issue: 03.05.2016
 Revision date: 17.03.2023 / Version/Replaced version: 2.0/1.0

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Dental gypsum, Type 1-5

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

- 1.1. Product identifier
 Product form: Mixture
 Product name: Dr. Balzer Special Plaster, Articulation plaster natural, Articulation plaster synthetic, Mounting Stone, Universal, Spezial, Dura semi-hard plaster, Neo Marmorit Super, Neo Marmorit, Neo Marmorit Speed, Neo Marmorit E, Modelit, Marmodent, Marmodent S, Natura, Ortho Plaster, Marmoplast N, Marmorock 20/22/24, Marmorock Speed, Japan-Stone, Neo Stone, Die Stone, Excalibur, Base Stone natur, Base Stone FL, CAM-Stone N, MarmoDie, Marmorock E, Marmorock Saphir.
- UFI: -
- 1.2. Relevant identified uses of the substance or mixture and uses advised against
 Relevant identified uses: Auxiliary for manufacture of dental prosthesis
- 1.3. Details of the supplier of the safety data sheet
 Manufacturer/Supplier: SILADENT Dr. Böhme & Schöps GmbH
 Street / mailbox: Im Klei 26
 Country code. / postal code / city: DE - 38644 Goslar
 Phone: +49 (0) 53 21 / 37 79 - 0
 Fax: +49 (0) 53 21 / 38 96 32
 E-mail / Website: info@siladent.de / www.siladent.de
 Further information obtainable from: SILADENT Dr. Böhme & Schöps GmbH
- 1.4. Emergency telephone number
 SILADENT Dr. Böhme & Schöps GmbH: +49 (0) 53 21 / 37 79 - 0 (Mon-Fri. 8 a.m. - 4 p.m.)

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture
 Classification according to Regulation (EC) No. 1272/2008 [CLP]
 Not classified
 Adverse physicochemical, human health and environmental effects:
 To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
- 2.2. Label elements
 Labelling according to Regulation (EC) No. 1272/2008 [CLP]:
 EUH phrases: EUH210 - Safety data sheet available on request.
- 2.3. Other hazards
 Results of PBT and vPvB assessment
 PBT: Not applicable.
 vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.1. Substances Not applicable
 - 3.2. Mixtures
 Description: Calcium sulphate, mineral fillers, non-hazardous admixtures
 Components:
- | | | |
|------------------------------------|------------------|-------------|
| CAS no: 7778-18-9 | Calcium sulphate | 90 - <100 % |
| EC no: 231-900-3 | Not classified | |
| REACH no:
01-2119444918-26-0066 | | |

Full text of H-statements: see section 16

SECTION 4: First aid measures

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| 4.1. | Description of first aid measures
First-aid measures general: | If you feel unwell, seek medical advice. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. In case of loss of conscience place the victim in the recovery position. |
| | First-aid measures after inhalation: | Remove victim to fresh air and keep at rest in a position comfortable for breathing. |
| | First-aid measures after skin contact: | Take off contaminated clothing and wash it before reuse. Wash with plenty of soap and water. |
| | First-aid measures after eye contact: | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| | First-aid measures after ingestion: | Rinse mouth. Drink water as a precaution. Get medical advice/attention if you feel unwell. |
| 4.2. | Most important symptoms and effects, both acute and delayed: | 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: | Treat symptomatically. |

SECTION 5: Firefighting measures

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| 5.1. | Extinguishing media
Suitable extinguishing media: | Adapt extinguishing agents to the environment. Foam. Dry powder. Carbon dioxide. Water spray. Sand. |
| | Unsuitable extinguishing media: | Do not use a heavy water stream. |
| 5.2. | Special hazards arising from the substance or mixture: | The product itself does not burn. Product cures after contact with water. |
| 5.3. | Advice for firefighters
Firefighting instructions: | Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment. |
| | Protection during firefighting: | Do not enter fire area without proper protective equipment, including respiratory protection. |

SECTION 6: Accidental release measures

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| 6.1. | Personal precautions, protective equipment and emergency procedures: | Provide adequate ventilation. Avoid breathing dust. Evacuate unnecessary personnel. Use personal protective equipment as required. Avoid dust formation. |
| 6.2. | Environmental precautions: | Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters. |
| 6.3. | Methods and material for containment and cleaning up: | On land, sweep or shovel into suitable containers. Take up mechanically and dry and collect in suitable container for disposal. |
| 6.4. | Reference to other sections: | Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13. |

SECTION 7: Handling and storage

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| 7.1. | Precautions for safe handling
Precautions for safe handling: | Ensure good ventilation of the work station. Avoid dust formation. Avoid breathing dust. Avoid contact with skin and eyes. |
| | Hygiene measures: | Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving |

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- work. Contaminated work clothing should not be allowed out of the workplace.
- 7.2. Conditions for safe storage, including any incompatibilities
 Storage conditions: Store in original container. Store tightly closed in a dry and cool place.
 Prohibitions on mixed storage: Keep away from food, drink and animal feedingstuffs.
 Storage class: 13 - Non-flammable solids
- 7.3. Specific end use(s): No additional information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	Components with critical values that require monitoring at the workplace:	
	7778-18-9 Calcium sulphate	
	OEL 8-hr (Ireland)	10 mg/m ³
	DNEL:	
	7778-18-9 Calcium sulphate	
	DNEL/DMEL (Workers)	
	Long-term - systemic effects, inhalation	21.17 mg/m ³
	Acute - systemic effects, inhalation	5082 mg/m ³
	DNEL/DMEL (General population)	
	Long-term - systemic effects, inhalation	5.29 mg/m ³
	Long-term - systemic effects, oral	1.52 mg/kg body weight/day
	Acute - systemic effects, inhalation	3811 mg/m ³
	Acute - systemic effects, oral	11.4 mg/kg body weight/day
	PNEC:	
	7778-18-9 Calcium sulphate	
	sewage treatment plant (STP):	100 mg/l

- 8.2. Exposure controls
- Appropriate engineering controls: Use adequate ventilation to keep vapour concentrations below applicable standard.
- Personal protective equipment:
- Hand protection: Wear suitable gloves (EN 374). Nitrile rubber. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection: Chemical goggles or safety glasses (EN 166).
- Respiratory protection: Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. In case of dust formation use respirator with filter: FFP1 (EN 149).
- Skin and body protection: Wear suitable protective clothing.
- Environmental exposure controls: Avoid release to the environment.

SECTION 9: Physical and chemical properties

- 9.1. Information on basic physical and chemical properties
- Physical state: Solid, crystalline Powder / Granulate
- Colour: Various
- Odour: Characteristic, weak
- Melting point/Freezing point: No data available
- Boiling point or initial boiling point and boiling range: No data available
- Flammability: Not flammable.
- Lower and upper explosion limit: Not applicable
- Flash point: Not applicable

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Auto-ignition temperature:	Not applicable
Decomposition temperature:	Ca. 1000 °C
pH:	7 - 9
Kinematic viscosity:	Not applicable
Solubility:	Water: 2 g/L
Partition coefficient n-octanol/water (log value):	Not applicable
Vapour pressure:	No data available
Density and/or relative density:	No data available
Relative vapour density:	Not applicable
Particle characteristics:	No data available
9.2. Other information	
Explosive properties:	No explosive properties.
Oxidising properties:	No oxidising properties.
Bulk density:	600 – 1200 kg/m ³

SECTION 10: Stability and reactivity

10.1. Reactivity:	No dangerous reactions known under normal conditions of use.
10.2. Chemical stability:	Stable under use and storage conditions as recommended in section 7. No decomposition if stored and applied as directed.
10.3. Possibility of hazardous reactions:	No hazardous reactions known under normal conditions of use.
10.4. Conditions to avoid:	No additional information available
10.5. Incompatible materials:	None known.
10.6. Hazardous decomposition products:	Decomposition at temperatures > 1000 °C. Release of calcium oxide and sulphur trioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008	
Acute toxicity:	Not classified Based on available data, the classification criteria are not met
Skin corrosion/irritation:	Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation:	Not classified Based on available data, the classification criteria are not met
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
Specific target organ toxicity (single exposure):	Not classified Based on available data, the classification criteria are not met

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Specific target organ toxicity (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
11.2. Information on other hazards Potential adverse human health effects and symptoms:	Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity	
Acute aquatic toxicity:	Not classified
Chronic aquatic toxicity:	Not classified
Ecology - general advice	Avoid release to the environment. Prevent entry to sewers and public waters.
12.2. Persistence and degradability:	No additional information available
12.3. Bioaccumulative potential:	No additional information available
12.4. Mobility in soil:	No additional information available
12.5. Results of PBT and vPvB assessment:	
PBT:	Not applicable.
vPvB:	Not applicable.
12.6. Endocrine disrupting properties:	No additional information available
12.7. Other adverse effects:	No other effects known

SECTION 13: Disposal considerations

13.1. Waste treatment methods	
Regional legislation (waste):	Dispose in a safe manner in accordance with local/national regulations.
Waste disposal recommendations:	When totally empty, containers are recyclable like any other packing.

European List of Waste (LoW) code	
10 12 00	wastes from manufacture of ceramic goods, bricks, tiles and construction products
10 12 06	discarded molds
10 13 00	wastes from manufacture of cement, lime and plaster and articles and products made from them
10 13 01	waste preparation mixture before thermal processing
10 13 06	particulates and dust (except 10 13 12 and 10 13 13)
17 08 00	gypsum-based construction material
17 08 02	gypsum-based construction materials other than those mentioned in 17 08 01

SECTION 14: Transport information

14.1. UN number or ID number ADR, IMDG, IATA:	Not applicable
14.2. UN proper shipping name ADR, IMDG, IATA:	Not applicable
14.3. Transport hazard class(es) ADR, IMDG, IATA:	Not applicable
14.4. Packing group ADR, IMDG, IATA:	Not applicable
14.5. Environmental hazards:	No
Marine pollutant:	No

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Other information:	No supplementary information available
14.6. Special precautions for user:	Not applicable.
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-Regulations
 This mixture is classified as not hazardous according to regulation (EC) 1272/2008.
 Contains no substance on the REACH candidate list.
 Contains no substance on the REACH Annex XIV List.
 National regulations
 No additional information available
- 15.2. Chemical safety assessment: A chemical safety assessment has been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
 The data given here only applies when product used for proper application(s). The product is not sold as suitable for other applications - usage in such may cause risks not mentioned in this sheet. Do not use for other application(s) without seeking advice from manufacturer.

Changes compared to the previous version:	Complete revision, adaptation to regulation (EU) 2020/878
Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative