

(Regulation (EC) n°1907/2006 - REACH)

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

- 1.1 Product identifier**  
**Product name:** Marmoplast BioStar
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
**Relevant identified uses:** Medical technology
- 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](mailto:info@siladent.de) / [www.siladent.de](http://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**  
**In compliance with EC regulation No. 1272/2008 and its amendments:** This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.  
This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).  
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.
- In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.** This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.  
This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).  
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.
- 2.2 Label elements:** In compliance with EC regulation No. 1272/2008 and its amendments.  
No labelling requirements for this mixture.
- 2.3 Other hazards:** The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC)  $\geq$  0.1% published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>  
The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

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**Marmoplast BioStar****SECTION 3: Composition/information on ingredients:****3.2 Mixtures****Composition:**

Identification	(CE) 1272/2008	67/548/CEE	Note	%
INDEX: PLASTER 1 CAS: 7778-18-9 EC: 231-900-3 REACH: 1- 2119444918-26-(0066)			(1)	[1] 90 <= x % < 100
SULFATE DE CALCIUM CASO4 + 0,5H2O				

[1] Substance for which maximum workplace exposure limits are available.

**SECTION 4: First aid measures:****General information:**

As a general rule, in case of doubt or if symptoms persist, always call a doctor.  
NEVER induce swallowing by an unconscious person.

**4.1 Description of first aid measures:****In the event of splashes or contact with eyes:**

Wash thoroughly with water for 15 minutes holding the eyelids open.  
If there is any redness, pain or visual impairment, consult an ophthalmologist.

**In the event of splashes or contact with skin:**

Wash with soap and water.

**In the event of swallowing:**

Seek medical attention, showing the label.

**4.2 Most important symptoms and effects, both acute and delayed:**

No specific symptoms or effects have been reported.

**4.3 Indication of any immediate medical attention and special treatment needed:**

None.

**SECTION 5: Firefighting measures:****Non-flammable.****5.1 Extinguishing media:****Suitable extinguishing media:**

Any means suitable for extinguishing surrounding fire.

**Unsuitable extinguishing media:**

None.

**5.2 Special hazards arising from the substance or mixture:**

None.

**5.3 Advice for firefighters:**

Product itself does not burn.  
Special protective equipment for fire-fighters: None.

**SECTION 6: Accidental release measures:****6.1 Personal precautions, protective equipment and emergency procedures:**

Consult the safety measures listed under headings 7 and 8.

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<b>For first aid worker:</b>	First aid workers will be equipped with suitable personal protective equipment (See section 8).
<b>6.2 Environmental precautions:</b>	Prevent any material from entering drains or waterways.
<b>6.3 Methods and material for containment and cleaning up:</b>	Retrieve the product by dry mechanical means (brush/vacuuming): do not generate dust.
<b>6.4 Reference to other sections:</b>	No data available.

**SECTION 7: Handling and storage:**

<b>7.1 Precautions for safe handling:</b>	Do not generate dust.
<b>Fire prevention:</b>	N/A Product itself does not burn.
<b>Recommended equipment and procedures:</b>	For personal protection, see section 8. Observe precautions stated on label and also industrial safety regulations.
<b>Prohibited equipment and procedures:</b>	N/A
<b>7.2 Conditions for safe storage, including any incompatibilities:</b>	Avoid the exposure to moisture
<b>Packaging</b>	Store in original packaging.
<b>7.3 Specific end use(s):</b>	No data available.

**SECTION 8: Exposure controls/personal protection**

<b>8.1 Control parameters</b>						
<b>Occupational exposure limits :</b>						
<b>- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :</b>	CAS TWA:	STEL:	Ceiling:	Definition:	Criteria:	
	7778-18-9	10 mg/m3	-	-	I	
<b>- Belgium (Order of 19/05/2009, 2010) :</b>	CAS TWA:	STEL:	Ceiling:	Definition:	Criteria:	
	7778-18-9	10 mg/m3	-	-	-	
<b>- France (INRS - ED984 :2012):</b>	CAS VME-ppm:	VME-mg/m3:	VLE-ppm:	VLE-mg/m3:	Notes:	TMP N°:
	7778-18-9	-	10	-	-	-
<b>Derived no effect level (DNEL) or derived minimum effect level (DMEL):</b>	<b>SULFATE DE CALCIUM CASO4 + 0,5H2O (CAS: 7778-18-9)</b>					
<b>Final use:</b>	Workers.					
<b>Exposure method:</b>	Inhalation.					
<b>Potential health effects:</b>	Short term systemic effects.					
<b>DNEL:</b>	5082 mg of substance/m3					
<b>Final use:</b>	Man exposed via the environment.					
<b>Exposure method:</b>	Ingestion.					
<b>Potential health effects:</b>	Short term systemic effects.					
<b>DNEL:</b>	11.4 mg/kg body weight/day					

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<b>Exposure method:</b>	Ingestion.
<b>Potential health effects:</b>	Long term systemic effects.
<b>DNEL:</b>	1.52 mg/kg body weight/day
<b>Exposure method:</b>	Inhalation.
<b>Potential health effects:</b>	Short term systemic effects.
<b>DNEL:</b>	3811 mg of substance/m <sup>3</sup>
<b>Exposure method:</b>	Inhalation.
<b>Potential health effects:</b>	Long term systemic effects.
<b>DNEL:</b>	
<b>Predicted no effect concentration (PNEC):</b>	SULFATE DE CALCIUM CASO <sub>4</sub> + 0,5H <sub>2</sub> O (CAS: 7778-18-9)
<b>Environmental compartment:</b>	Waste water treatment plant.
<b>PNEC:</b>	100 mg/l

- 8.2 Exposure controls**  
**Personal protection measures, such as personal protective equipment**  
**Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE):** None

Do not generate dust. Use personal protective equipment that is clean and has been properly maintained. Ensure that there is adequate ventilation, especially in confined areas.

<b>Eye protection:</b>	Avoid contact with eyes. In case of splashing, wear protective goggles in accordance with standard EN166.
<b>Hand protection:</b>	Wear suitable protective gloves in the event of prolonged or repeated skin contact.
<b>Body protection:</b>	Work clothing.
<b>Respiratory protection:</b>	Avoid breathing dust. Type of FFP mask: Wear a disposable half-mask dust filter in accordance with standard EN149.

**SECTION 9: Physical and chemical properties:****9.1 Information on basic physical and chemical properties:**

<b>General information:</b>		
<b>Physical state:</b>	Powder	
<b>Important health, safety and environmental information</b>		
<b>pH:</b>	N/A, mixed with water 7-9	
<b>Boiling point</b>	N/A	
<b>Flash point (50°C):</b>	N/A	
<b>Vapour pressure:</b>	N/A	
<b>Density:</b>	600-1200.	
<b>Water solubility:</b>	Soluble. app. 2g/l	
<b>Melting point/melting range:</b>	N/A	
<b>Self-ignition temperature:</b>	no self ignition/ not explosive	
<b>Decomposition point/decomposition range :</b>		
in CaSO <sub>4</sub> x ½ H <sub>2</sub> O und H <sub>2</sub> O	ca. 140°C	(ca. 413 K)
in CaO und SO <sub>3</sub>	ca. 1000°C	(ca. 1273 K)

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**9.2 Other information:** No data available.

### SECTION 10: Stability and reactivity:

- 10.1 Reactivity:** No data available.
- 10.2 Chemical stability:** This mixture is stable under the recommended handling and storage conditions in section 7.
- 10.3 Possibility of hazardous reactions:** Mixing with an aqueous solution of sodium carbonate will result in the formation of carbon dioxide.
- 10.4 Conditions to avoid:** Avoid:  
- formation of dusts
- 10.5 Incompatible materials:** None known.
- 10.6 Hazardous decomposition products:** Decomposition > 1000°C : Sulfurtrioxide and Calciumoxide

### SECTION 11: Toxicological information:

**11.1 Information on toxicological effects:** No data available.

**Acute toxicity:** Not classified

#### 11.1.1 Substances

**Acute toxicity :**

SULFATE DE CALCIUM CASO<sub>4</sub> + 0,5H<sub>2</sub>O (CAS: 7778-18-9)

**Oral route:** LD<sub>50</sub> > 1581 mg/kg  
Species : Rat

OECD Guideline 420 (Acute Oral Toxicity Fixed Dose Method)

Inhalation route: LC<sub>50</sub> > 2.61 mg/l

Species: Rat

OECD Guideline 403 (Acute Inhalation Toxicity)

**Skin corrosion/skin irritation:**

SULFATE DE CALCIUM CASO<sub>4</sub> + 0,5H<sub>2</sub>O (CAS: 7778-18-9)

Corrosivity: No observed effect.

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

**Serious damage to eyes/eye irritation:**

SULFATE DE CALCIUM CASO<sub>4</sub> + 0,5H<sub>2</sub>O (CAS: 7778-18-9)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

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### Respiratory or skin sensitisation:

SULFATE DE CALCIUM CASO4 + 0,5H2O (CAS: 7778-18-9)

Local lymph node stimulation test : Non-Sensitiser.

Species: Guinea pig

OECD Guideline 406 (Skin Sensitisation)

Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.

Species: Guinea pig

OECD Guideline 406 (Skin Sensitisation)

Buehler Test: Non-sensitiser.

Species: Guinea pig

OECD Guideline 406 (Skin Sensitisation)

### Germ cell mutagenicity:

SULFATE DE CALCIUM CASO4 + 0,5H2O (CAS: 7778-18-9)

No mutagenic effect.

Mutagenesis (in vivo): Negative.

Species: Mouse

OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Mutagenesis (in vitro): Negative.

### Carcinogenicity:

SULFATE DE CALCIUM CASO4 + 0,5H2O (CAS: 7778-18-9)

Carcinogenicity Test: Negative.

No carcinogenic effect.

### Reproductive toxicant:

SULFATE DE CALCIUM CASO4 + 0,5H2O (CAS: 7778-18-9)

No toxic effect for reproduction

Study on development : Species : Rat

OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity

Screening Test) Mutagénèse (in vivo): Negative.

**11.1.2 Mixture:** No toxicological data available for the mixture

## SECTION 12: Ecological information:

### 12.1.1 Substances

SULFATE DE CALCIUM CASO4 + 0,5H2O (CAS: 7778-18-9)

Fish toxicity: LC50 > 79 mg/l

Species: Others

DuraHon of exposure: 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity: EC50 > 79 mg/l

Species: Daphnia sp.

DuraHon of exposure: 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity: ECr50 > 79 mg/l

Species: Selenastrum capricornutum

DuraHon of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

**12.1.2 Mixtures:** No aquatic toxicity data available for the mixture.

### 12.2 Persistence and degradability

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### 12.2.1 Substances

SULFATE DE CALCIUM CASO<sub>4</sub> + 0,5H<sub>2</sub>O (CAS: 7778-18-9)

Biodegradability: no degradability data is available, the substance is considered as not degrading quickly.

- 12.3 Bioaccumulative potential:** No data available.
- 12.4 Mobility in soil:** No data available.
- 12.5 Results of PBT and vPvB assessment:** No data available.
- 12.6 Other adverse:** No data available.

### SECTION 13: Disposal considerations:

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Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

- 13.1 Waste treatment methods** Do not pour into drains or waterways.  
Waste :  
Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals. Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste, do not dispose of waste into the environment.
- Soiled packaging:** Empty container completely. Keep label(s)

### SECTION 14: Transport information:

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Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014)

### SECTION 15: Regulatory information:

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- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
**Classification and labelling information included in section 2:**

**The following regulations have been used:**

- Directive 67/548/EEC and its adaptations

Directive 1999/45/EC and its adaptations

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014

**Container information:** No data available.

**Particular provisions:** No data available.

- 15.2 Chemical safety assessment:** A chemical safety assessment has been carried out.

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**SECTION 16: Other information:**

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

**In compliance with directives  
67/548/EEC, 1999/45/EC and their  
amendments:**

No labelling requirements for this mixture.

**Abbreviations:**

DNEL : Derived No-Effect Level

PNEC : Predicted No-Effect Concentration

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.