

# SAFETY DATA SHEET



according to Regulation (EC) No 1907/2006 (REACH) as amended

## Calcium sulfate dihydrate, natural

Creation date 04th September 2023  
Revision date 30th August 2024 Version 1.1

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

**1.1. Product identifier**  
Substance / mixture Calcium sulfate dihydrate, natural substance  
Chemical name Calcium Sulfate Dihydrate  
CAS number 13397-24-5  
EC (EINECS) number 603-783-2  
Registration number -----

**1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Substance's intended use**

Food supplement. Ingredient for cosmetics. Special applications.

**Substance uses advised against**

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**1.3. Details of the supplier of the safety data sheet**

**Distributor**

Name or trade name Macco Organiques, s.r.o.  
Address Zahradní 1938/46c, Bruntál 1, 792 01  
Czech Republic  
Identification number (CRN) 26819210  
VAT Reg No CZ26819210  
Phone +420 555 530 300  
E-mail macco@macco.cz

**Competent person responsible for the safety data sheet**

Name Petr Ševčík  
E-mail petr.sevcik@macco.cz

**1.4. Emergency telephone number**

European emergency number: 112

### SECTION 2: Hazards identification

**2.1. Classification of the substance or mixture**

**Classification of the substance in accordance with Regulation (EC) No 1272/2008**

The substance is not classified as dangerous according to Regulation (EC) No 1272/2008.

**Most serious adverse physico-chemical effects**

Not specified.

**Most serious adverse effects on human health and the environment**

Not specified.

**2.2. Label elements**

**Signal word**

none

**2.3. Other hazards**

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Substance does not meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

### SECTION 3: Composition/information on ingredients

**3.1. Substances**

**Chemical characterization**

The substance specified below.

| Identification numbers  | Substance name   | Content in % weight | Classification according to Regulation (EC) No 1272/2008 | Note |
|---|--|---------------------|--|------|
| CAS: 13397-24-5<br>EC: 603-783-2<br>Registration number:<br>----- | <b>substance main component</b><br>Calcium Sulfate Dihydrate | 99-100              | not classified as dangerous                              |      |

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Full text of all classifications and hazard statements is given in the section 16.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Take care of your own safety. In the event of unconsciousness, do not provide food by mouth. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

##### If inhaled

Transfer the affected person to the fresh air and ensure calm environment for body and mind. Depending on the situation, call the medical rescue service and always ensure medical treatment.

##### If on skin

Remove contaminated clothes. And wash it before reuse. Wash the affected area with plenty of water, lukewarm if possible. Provide medical treatment if skin irritation persists.

##### If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. No neutralization should be performed in any case! Provide medical treatment, specialized if possible.

##### If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help. DO NOT INDUCE VOMITING!

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

##### If inhaled

May cause respiratory irritation.

##### If on skin

Irritation, itching, redness.

##### If in eyes

Not expected.

##### If swallowed

Not expected.

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

Symptomatic treatment.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. Accommodate extinguishing components to the location of fire.

##### Unsuitable extinguishing media

Not defined.

#### 5.2. Special hazards arising from the substance or mixture

At high temperatures, decomposition occurs to form sulfur dioxide.

#### 5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Do not inhale dust. Provide sufficient ventilation. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8.

#### 6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

#### 6.3. Methods and material for containment and cleaning up

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

#### 6.4. Reference to other sections

See the Section 7, 8 and 13.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Prevent formation of dust in concentrations exceeding the occupational exposure limits. Do not eat, drink or smoke when using this product. Prevent contact with skin and eyes. Use personal protective equipment as per Section 8. Wash hands and exposed parts of the body thoroughly after handling. Observe valid legal regulations on safety and health protection.

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

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

#### 7.3. Specific end use(s)

not available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Not specified.

##### DNEL

| Calcium Sulfate Dihydrate |                   |                         |                          |
|---------------------------|-------------------|-------------------------|--------------------------|
| Workers / consumers       | Route of exposure | Value                   | Effect                   |
| Workers                   | Inhalation        | 5082 mg/m <sup>3</sup>  | Acute effects systemic   |
| Workers                   | Inhalation        | 21.17 mg/m <sup>3</sup> | Chronic effects systemic |
| Consumers                 | Oral              | 11.4 mg/kg bw/day       | Acute effects systemic   |
| Consumers                 | Oral              | 1.52 mg/kg bw/day       | Chronic effects systemic |
| Consumers                 | Inhalation        | 3811 mg/m <sup>3</sup>  | Acute effects systemic   |
| Consumers                 | Inhalation        | 5.29 mg/kg bw/day       | Chronic effects systemic |

##### PNEC

| Calcium Sulfate Dihydrate          |          |
|------------------------------------|----------|
| Route of exposure                  | Value    |
| Microorganisms in sewage treatment | 100 mg/l |

#### 8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest. Follow the usual measures intended for health protection at work and especially for good ventilation. Provide showers and eye wash possibility.

##### Eye/face protection

Protective goggles or face shield (based on the nature of the work performed).

##### Skin protection

When handling in long-term or repeatedly, use protective gloves. EN ISO 374-1.

##### Respiratory protection

Respirator. Half-mask with anti-dust filter when the exposition limits of substances are exceeded or in the location with insufficient ventilation.

##### Thermal hazard

Not available.

##### Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

|                              |                   |
|------------------------------|-------------------|
| Physical state               | solid             |
| Colour                       | white             |
| Odour                        | without fragrance |
| Melting point/freezing point | 128 °C            |

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Boiling point or initial boiling point and boiling range cannot be determined - decomposition occurs  
Flammability non-flammable  
Lower and upper explosion limit not applicable  
Flash point not applicable  
Auto-ignition temperature not applicable  
Decomposition temperature 128 °C  
pH 5-7.5 (0.26% solution at 20 °C)  
Kinematic viscosity not applicable  
Solubility in water 0.26g / 100g 20°C  
Partition coefficient n-octanol/water (log value) not applicable  
Vapour pressure not applicable  
Density and/or relative density  
Density 2.32 g/cm<sup>3</sup> at 20 °C  
Relative vapour density not applicable  
Particle characteristics data not available  
Form solid: particulate/powder

### 9.2. Other information

Oxidising properties It is not oxidising.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The substance is non-flammable.

### 10.2. Chemical stability

The product is stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Unknown.

### 10.4. Conditions to avoid

Humid air. Heat.

### 10.5. Incompatible materials

Aluminium. Diazomethane

### 10.6. Hazardous decomposition products

Not developed under normal uses.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the substance.

#### Acute toxicity

Based on available data the classification criteria are not met.

| Calcium Sulfate Dihydrate |                  |          |                   |               |                                  |     |
|---------------------------|------------------|----------|-------------------|---------------|----------------------------------|-----|
| Route of exposure         | Parameter        | Method   | Value             | Exposure time | Species                          | Sex |
| Oral                      | LD <sub>50</sub> | OECD 420 | >2000 mg/kg       |               | Rat ( <i>Rattus norvegicus</i> ) | F   |
| Inhalation (dust/mist)    | LC <sub>50</sub> | OECD 403 | >3.26 mg/l of air | 4 hours       | Rat ( <i>Rattus norvegicus</i> ) | F/M |

#### Skin corrosion/irritation

Based on available data the classification criteria are not met.

| Calcium Sulfate Dihydrate |                |          |               |         |
|---------------------------|----------------|----------|---------------|---------|
| Route of exposure         | Result         | Method   | Exposure time | Species |
| Dermal                    | Not irritating | OECD 404 | 4 hours       | Rabbit  |

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### Serious eye damage/irritation

Based on available data the classification criteria are not met.

| Calcium Sulfate Dihydrate |                |          |               |         |
|---------------------------|----------------|----------|---------------|---------|
| Route of exposure         | Result         | Method   | Exposure time | Species |
| Eye                       | Not irritating | OECD 405 | 1 hour        | Rabbit  |

### Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

| Calcium Sulfate Dihydrate |                 |          |               |   |     |
|---------------------------|-----------------|----------|---------------|---|-----|
| Route of exposure         | Result          | Method   | Exposure time | Species   | Sex |
| Skin                      | Not sensitizing | OECD 406 | 6 hours       | Guinea-pig ( <i>Cavia aperea f. porcellus</i> ) | M   |

### Germ cell mutagenicity

Based on available data the classification criteria are not met.

| Calcium Sulfate Dihydrate |          |               |                       |  |     |
|---------------------------|----------|---------------|-----------------------|--|-----|
| Result                    | Method   | Exposure time | Specific target organ | Species                                    | Sex |
| Negative                  | OECD 472 |               |                       | Bacteria ( <i>Salmonella typhimurium</i> ) |     |
| Negative                  | OECD 474 | 1 day         |                       | Mouse                                      | M   |

### Carcinogenicity

No data available for the substance. Based on available data the classification criteria are not met.

### Reproductive toxicity

Based on available data the classification criteria are not met.

| Calcium Sulfate Dihydrate |                           |          |                   |                              |           |                                  |     |
|---------------------------|---------------------------|----------|-------------------|------------------------------|-----------|----------------------------------|-----|
| Effect                    | Parameter                 | Method   | Value             | Exposure time                | Result    | Species                          | Sex |
| Effects on fertility      | NOAEL (P/F <sub>1</sub> ) | OECD 422 | 1000 mg/kg bw/day | 35, 41-45 days (7 days/week) | No effect | Rat ( <i>Rattus norvegicus</i> ) | F/M |
| Developmental toxicity    | NOAEL                     | OECD 414 | 2024 mg/kg bw/day | 10 days (7 days/week)        | No effect | Rat ( <i>Rattus norvegicus</i> ) | F   |

### Toxicity for specific target organ - single exposure

No data available for the substance. Based on available data the classification criteria are not met.

### Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

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### Repeated dose toxicity

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|---------------------------|-----------|-----------|----------|-------------------------|-----------------------------------|-------------------------|-----|
| Route of exposure         | Parameter | Result    | Method   | Value                   | Exposure time                     | Species                 | Sex |
| Oral                      | NOAEL     | No effect | OECD 422 | 1000 mg/kg bw/day       | 41-45 days (7 days/week)          | Rat (Rattus norvegicus) | F   |
| Inhalation (aerosols)     |           | No effect | in vivo  | 126.5 mg/m <sup>3</sup> | 3 weeks (5 days/week, 6 hour/day) | Rat (Rattus norvegicus) | M   |

### Aspiration hazard

No data available for the substance. Based on available data the classification criteria are not met.

### 11.2. Information on other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## SECTION 12: Ecological information

### 12.1. Toxicity

Based on available data the classification criteria are not met.

#### Acute toxicity

| Calcium Sulfate Dihydrate |            |               |                                   |             |
|---------------------------|------------|---------------|-----------------------------------|-------------|
| Parameter                 | Value      | Exposure time | Species                           | Environment |
| LC <sub>50</sub>          | >3769 mg/l | 96 hours      | Fish (Lepomis macrochirus)        |             |
| LC <sub>50</sub>          | >2491 mg/l | 48 hours      | Crustaceans (Daphnia magna)       |             |
| EC <sub>50</sub>          | >100 mg/l  | 72 hours      | Algae (Selenastrum capricornutum) |             |

#### Chronic toxicity

| Calcium Sulfate Dihydrate |          |           |               |         |                  |
|---------------------------|----------|-----------|---------------|---------|------------------|
| Parameter                 | Method   | Value     | Exposure time | Species | Environment      |
| NOEC                      | OECD 209 | 1000 mg/l | 3 hours       |         | Activated sludge |

### 12.2. Persistence and degradability

No data available for the substance.

### 12.3. Bioaccumulative potential

No data available for the substance.

### 12.4. Mobility in soil

No data available for the substance.

### 12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

### 12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

### 12.7. Other adverse effects

Not available.

## SECTION 13: Disposal considerations

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### 13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

#### Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

#### Waste type code

06 03 14 solid salts and solutions other than those mentioned in 06 03 11 and 06 03 13

#### Packaging waste type code

06 02 99 wastes not otherwise specified

## SECTION 14: Transport information

### 14.1. UN number or ID number

not subject to transport regulations

### 14.2. UN proper shipping name

not relevant

### 14.3. Transport hazard class(es)

not relevant

### 14.4. Packing group

not relevant

### 14.5. Environmental hazards

not relevant

### 14.6. Special precautions for user

Reference in the Sections 4 to 8.

### 14.7. Maritime transport in bulk according to IMO instruments

not relevant

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

### 15.2. Chemical safety assessment

Not available. Exempted from REACH registration in accordance with Annex V.7.

## SECTION 16: Other information

### Other important information about human health protection

The user is responsible for adherence to all related health protection regulations.

### Key to abbreviations and acronyms used in the safety data sheet

|     |   |
|-----|---|
| ADR | European agreement concerning the international carriage of dangerous goods by road               |
| BCF | Bioconcentration Factor   |
| CAS | Chemical Abstracts Service  |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures |

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|                     |   |
|---------------------|---|
| EC                  | Identification code for each substance listed in EINECS   |
| EC <sub>50</sub>    | Concentration of a substance when it is affected 50 % of the population                           |
| EINECS              | European Inventory of Existing Commercial Chemical Substances                                     |
| EmS                 | Emergency plan  |
| EU                  | European Union  |
| EuPCS               | European Product Categorisation System  |
| IATA                | International Air Transport Association   |
| IBC                 | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals       |
| ICAO                | International Civil Aviation Organization   |
| IMDG                | International Maritime Dangerous Goods  |
| IMO                 | International Maritime Organization   |
| INCI                | International Nomenclature of Cosmetic Ingredients  |
| ISO                 | International Organization for Standardization  |
| IUPAC               | International Union of Pure and Applied Chemistry   |
| LC <sub>50</sub>    | Lethal concentration of a substance in which it can be expected death of 50% of the population    |
| LD <sub>50</sub>    | Lethal dose of a substance in which it can be expected death of 50% of the population             |
| log K <sub>ow</sub> | Octanol-water partition coefficient   |
| NOAEL               | No observed adverse effect level  |
| NOEC                | No observed effect concentration  |
| OEL                 | Occupational Exposure Limits  |
| PBT                 | Persistent, bioaccumulative and toxic   |
| ppm                 | Parts per million   |
| REACH               | Registration, Evaluation, Authorisation and Restriction of Chemicals                              |
| RID                 | Agreement on the transport of dangerous goods by rail   |
| UN                  | Four-figure identification number of the substance or article taken from the UN Model Regulations |
| UVCB                | Substances of unknown or variable composition, complex reaction products or biological materials  |
| VOC                 | Volatile organic compounds  |
| vPvB                | Very persistent and very bioaccumulative  |

### Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

### Recommended restrictions of use

not available

### Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.  
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

### The changes (which information has been added, deleted or modified)

The version 1.1 replaces the SDS version from Monday, 4 September 2023. Changes were made in sections 1, 8, 11,12 and 16.

### Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.