

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

- 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 EC: 603-783-2 Registration number: -----	substance main component Calcium Sulfate Dihydrate	99-100	not classified as dangerous	

SAFETY DATA SHEET



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

Calcium sulfate dihydrate, natural

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

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.

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 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 ³	Acute effects systemic
Workers	Inhalation	21.17 mg/m ³	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 ³	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

SAFETY DATA SHEET



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

Calcium sulfate dihydrate, natural

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

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 ³ 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.
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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 ₅₀	OECD 420	>2000 mg/kg		Rat (Rattus norvegicus)	F
Inhalation (dust/mist)	LC ₅₀	OECD 403	>3.26 mg/l of air	4 hours	Rat (Rattus norvegicus)	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

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

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 (Cavia aperea f. porcellus)	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 (Salmonella typhimurium)	
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 ₁)	OECD 422	1000 mg/kg bw/day	35, 41-45 days (7 days/week)	No effect	Rat (Rattus norvegicus)	F/M
Developmental toxicity	NOAEL	OECD 414	2024 mg/kg bw/day	10 days (7 days/week)	No effect	Rat (Rattus norvegicus)	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.

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

Repeated dose toxicity

Calcium Sulfate Dihydrate							
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 ³	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 ₅₀	>3769 mg/l	96 hours	Fish (Lepomis macrochirus)	
LC ₅₀	>2491 mg/l	48 hours	Crustaceans (Daphnia magna)	
EC ₅₀	>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

SAFETY DATA SHEET



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

Calcium sulfate dihydrate, natural

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

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

SAFETY DATA SHEET



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

Calcium sulfate dihydrate, natural

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

EC	Identification code for each substance listed in EINECS
EC ₅₀	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 ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	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.