Safety Data Sheet

According to Regulation (EC) No 1907/2006 and (EU) No. 453/2010

Issue date : September 17.1999 Revision # 10, date : August 13, 2018

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

1.1 Product identifier :

Trade name:	**Calcium chloride dihydrate**
Chemical name:	Calcium chloride dihydrate
Identification number:	CAS No: 10035-04-8
Registration number:	01-2119494219-28-0006

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

Identified uses:	infusion solutions, hemodialysis solutions, mineral supplement, see Annex I. to this SDS.
Uses advised against:	No uses advised against are identified.

1.3 Details of the supplier of the safety data sheet :

Macco Organiques, s. r.o.
Zahradní 46c, 792 01 Bruntál, Czech Republic
IČ : 26819210 , phone: +420 – 555 – 530 334
SDS provider´s contact: Jaroslav Zavadil , phone: +420 – 555 – 530 340, jaroslav.zavadil@macco.cz

1.4 Emergency telephone number :

The first aid details may be consulted with toxicological information centre (TIS): Job-related illness clinic, Na Bojišti 1, 128 08 Praha 2, tel. 2 24 91 92 93 or 2 24 91 54 02. Permanent poisoning informations.

2: Hazard identification

The substance **is classified as dangerous** according to Directive 1272/2008/ES.

2.1 Classification of the substance or mixture :

Acc. to Directive 1272/2008/ES	Eye Irrit. 2; H319

The most important adverse physicochemical, human health and environmental effects and symptoms :

May be harmful on ingestion. May cause nausea, vomiting, irritation of skin, eyes and respiratory tract.

The information shown on the label shall be given under heading 15.

2.2 Label elements :

Hazard pictogram		*Signal word*	**Warning**
Hazard statements	H319 Causes serious eye irritation.		
Precautionary statements	P264, P280, P305 + P351 + P338, P 337 + P313 Full version of P sentences is stated in section 15.		
Additional information on label	none		

2.3 Other hazards :

Substance is NOT classified as PBT or vPvB. Calcium chloride can cause minor skin irritation and dry skin.

3: Composition / information on ingredients

3.1 Substances :

3.1.1 Constituent

Chemical identity	*Index No.*	*CAS*	*EINECS*	*concentration*	*classification list number*
Calcium chloride dihydrate	none	10035-04-8	233-140-8	99 – 103%	So far none

***3.1.2* Impurities, stabilizers,**

Chemical identity	*Index No.*	*CAS*	*EINECS*	*concentration*	*classification list number*
none	- - -	- - -	- - -	- - -	- - -
3.2 Mixtures :	irrelevant				

4: First aid measures

In all cases provide the physical and mental rest and avoid of getting chilled. In case of health problems or doubts inform physician and provide him with the information contained in this safety data sheet**.** Never pass a medication to a unconscious person. Maintain personal safeness during rescue operation.

4.1 Description of first aid measures :

If inhaled:

Stop exposition, move the afflicted person to the fresh air, keep him warm and at rest. If symptoms persist seek medical attention. In case of unconsciousness start with resuscitation (artificial respiration, cardiac massage) and call for medical attention.

In the event of skin contact:

Remove contaminated clothes and footwear. Wash of any skin contamination with cool water and soap. Launder clothes before re-use. In case of persisting irritation contact physician .

In the event of eye contact:

Remove contact lenses if present. Rinse with a small amount of water for at least 10 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Seek medical attention.

Do not use neutralization solution!

If swallowed:

Wash out mouth with water and give plenty of water to drink (at least 300 ml). Do not induce vomiting. Seek medical attention. When vomiting, maintain supervision until the help arrives. Obtain medical advice if symptoms persist.

4.2 Most important symptoms and effects, both acute and delated :

Skin , airways or eye irritation. After consumption of a bigger amount vomiting and diarrhoea, alimentary tract irritation may appear. Symptoms: red skin, eyes, blurred vision.

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

DO NOT induce vomiting. The product could be strengthened with the hydrogen chloride from the stomach and cause irritation on oesophagus or it might irritate the respiratory system. Wash out mouth with water and give plenty of water to drink (at least 300 ml) and observe the patient.

5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Non-combustible substance . All extinguishing media are allowed, select the appropriate extinguishing media depending on the surrounding fire and environment.

Not suitable extinguishing media :

Strong water jet

5.2 Specific hazards arising from the substance or mixture:

Non-combustible substance. When warmed up, irritable or toxic gases may occure.

5.3 Advice for firefighters:

Use individual breathing apparatus, anti-gas safety clothing.

6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal safety working clothes – section 8. Prevent from skin and eye contact. Do not inhale dust. Well ventilate areas. Prevent from dust making. Other safety precautions – section 7.

6.2 Environmental precautions:

Prevent from escape to watercourses and soil and from their contamination. If there is no way to avoid it, immediately inform appropriate authority (police and firemen).

See exposure scenarios covering intended use in the environment.

6.3 Methods and material for containment and cleaning up:

Clean up contamination/spillages as soon as they occur. Collect as much as possible in a suitable clean container, preferably for re-use, otherwise for disposal (according section 13). Avoid generation of dust. Wash the spillage area with large quantities of water. When packaging is damaged, replace the amount into a new packaging with proper marking.

6.4 References to other sections:

Also follow the regulations in sections 8 and 13 of this safety data sheet.

7: Handling and storage

7.1 Precautions for safe handling:

Use the personal safety tools (section 8). Ensure fresh water for the first aid. Maintain the cleanness and tidiness on the working area. Provide basic employee training to prevent / minimize exposures and to report any health problems that may develop. Do not eat, drink or smoke during work. Avoid contact with skin and eyes. Wash hands duly with soap and water, take a shower. Use a body lotion.

7.2 Conditions for safe storage, including any incompatibilities:

Store at a dry place, not above normal room temperature. Avoid excessive ventilation as the product can absorb moisture from the air**.** Calcium chloride liquors can cause corrosion of some grades of stainless steel and under high temperature and stress conditions can promote stress corrosion cracking. Calcium chloride is highly hydroscopic.

7.3 Specific end uses:

Industrial chemical, component of infusion and dialysis solutions and food supplements. For more information see the "Exposure Scenarios", as the enclosure of this SDS.

8: Exposure controls / personal protection

8.1 Control parameters

8.1.1 Exposure limits

Dust (inhalable amount of any dust) - Workplace Exposure Limit (WEL) 8h: 10 mg/ m^3
Respirable dust - Workplace Exposure Limit (WEL) 8h: 4 mg/ m^3

8.1.2 Biological limit values:

- not specified

8.1.3 DNEL and PNEC values (data assumed from anhydrous calcium chloride) :

Derived No Effect Level (DNEL)

- Worker DNEL inhalation, long term 5 mg/ m^3 (ES9)
- Worker DNEL inhalation, short term 10 mg/ m^3 (ES9)
- Consumer, general population DNEL inhalation – long term 2.5 mg/ m^3 (ES10, not included in this SDS)
- Consumer, general population DNEL inhalation – short term 5 mg/ m^3 (ES10, not included in this SDS)

Predicted No Effect Concentration (PNEC)

- Deposition onto soil and plants*): NE_{dep} 150 g/ m^2. If the product is used for de-icing or dust control, see ES7.
- Sensitive terrestrial plants: 215 mg chloride/kg. If the product is used for de-icing or dust control, see ES7.
- PNEC water/marine: because the calcium and chloride concentration varies between aquatic ecosystems (0.06-210 mg/L), it is not considered useful to derive a generic PNEC water or PNEC marine (neither added or intermittent values).
- PNEC fresh water/marine sediment: no toxicity data on fresh water or marine sediment organisms are available. Calcium chloride is present in the environment as calcium and chloride ions, which implies that it will not adsorb on particulate matter. It is not considered useful to derive a PNEC fresh water or PNEC marine sediment.
  PNEC terrestrial: no toxicity data on terrestrial organisms are available. Calcium chloride is present in the environment as calcium and chloride ions, which implies that it will not adsorb on particulate matter. It is not considered useful to derive a PNEC terrestrial.
- PNEC sewage treatment plant (STP): no toxicity data on sewage treatment plant organisms are available. Because the calcium and chloride concentration varies between aquatic ecosystems, it is not considered useful to derive a generic PNEC STP or PNEC STP-added.

- PNEC oral: in view of the nutritional aspects, the metabolism and the mechanisms of action of calcium and chloride ions, it is not considered useful to derive a PNEC oral (secondary poisoning).

**) A tentative PNEC, a so-called "no-effect deposition"(NEdep) was derived for the exposure route for deposition of calcium chloride via road salts or dust suppressors. It should be noted that although the units refer to exposure via air, this value reflects effects caused by calcium chloride from air into soil or onto plants' surface.*

8.2 Exposure control

8.2.1 Occupational exposure control:

See relevant exposure scenarios for different intended uses. Operate in a well-ventilated area, avoid inhalation of dusts or mists (for liquids). Atmospheric levels should be controlled in compliance with the exposure scenarios and occupational exposure limits. Ensure shower and area for eyes rinsing. The mentioned personal safety instruments should be in compliance with EN standards.

Personal protective equipment:

Respiratory protection:	In the case of high dust levels wear suitable respiratory protective equipment, ie. dust mask or respirator conforming to EN standards. Recommended filter = particle filter,P2.
Hand protection:	Wear suitable chemical resistant protective gloves for frequent or prolonged operations tested to EN374 with an acceptable permeation test. Suitable materials include neoprene (chloroprene), PVC and nitrile rubber. Break through time is > 480 min. Contaminated gloves should be carefully rinsed with water before reuse. Non suitable materials: Leather gloves.
Eye / face protection:	Wear suitable eye/face protection. Most materials for protective googles and face visors will probably be suitable eg. polycarbonate.
Skin and body protection:	Normal working clothes is suitable.

Do not eat, drink or smoke during work. Immediately remove contaminated clothing. Wash hands duly with soap and water, take a shower. Use a body lotion.

8.2.2 Environmental exposure controls:

Prevent from escape to environment (see appropriate Exposure Scenarios).

9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state (at 20 °C):		Solid - crystals
Colour:		Colorless up to white
Odour (fragrance):		odourless
Treshold odour value:		odourless

9.2 Other information:

pH (at 20 °C):		5 – 8 (5 % solution at 20 °C)
Melting point:		176 °C
Boiling point:		Not applicable
Flash point:		Not applicable, incombustible matter
Evaporation rate:		Not applicable
Flamability** (solid, gas) **:		The substance is non-flammable
Explosion limits	*lower:* *upper:*	Not available, non-explosive matter Not available, non-explosive matter
Vapour pressure:		irrelevant
Vapour density:		irrelevant
Relative density:		1,835 g/cm^3
Water solubility (at 20 °C) :		130 g / 100 ml
Solubility in solvents:		Not available
Partition coefficient n-octanol/water:		Not available
Self-ignition temperature:		Not applicable
Decomposition temperature:		260 °C
Viscosity:		Not applicable
Explosive properties:		The substance is non-explosive

Oxidizing properties:	The substance is non-oxidizing
Fat solubility:	Not available
Conductivity:	Not available
Gas group:	Not applicable

10: Stability and reactivity

10.1 Reactivity:

Hydroscopic substance, risk of exothermic reaction or reaction with strong reducing or oxidizing agents.

10.2 Chemical stability:

Stable under recommended storage and handling conditions. Strong oxidizing agents generates chlorine.

10.3 Possibility of hazardous reactions:

Exothermic reaction with water, reaction with strong oxidizing agents generates chlorine.

10.4 Conditions to avoid:

Humidity and moisture, strong reducing and oxidizing agents

10.5 Incompatible materials :

Strong reducing and oxidizing agents, boron trifluoride, vinylmethyl ether. Calcium chloride can cause corrosion of some grades of stainless steel. High temperature and stress conditions can promote stress corrosion cracking

10.6 Hazardous decomposition products:

None at normal use. Irritant or toxic gases can be generated at higher temperature (over 260 °C). Generates dangerous gases or fumes in contact with metals, zinc (generation of hydrogen).

11: Toxicological information

11.1 Information on toxicological effects:

Acute toxicity:	
- LD_{50} oral, rat (mg.kg^{-1}):	3000 (mouse 2700, rabbit 1000)
- LD_{50} dermal, rabbit (mg.kg^{-1}):	> 6500
- LC_{50} inhalation, rat, for aerosols or particles (mg.l^{-1}):	Not specified
Skin irritation:	No irritation
Eye irritation:	Eye irritation, Eye irrit. cat. 2
Sensitisation:	Substance does not have sensitive effects on skin and respiratory system
Carcinogenicity:	Not carcinogenic substance
Mutagenicity:	Not mutagenic substance
Toxicity for reproduction:	Not toxic substance for reproduction
Toxicity for specific target body – single exposition	Substance does not have toxic effects within single exposition
Toxicity for specific target body – repeated exposition:	Substance does not have toxic effects within repeated exposition
Irritation if inhaled:	Substance does not have irritable effects

Other information: none

12: Ecological information

12.1 Toxicity:

- LC_{50} 96 hr., fish (mg.l^{-1}):	6000
- EC_{50} 48 hr., daphnia (mg.l^{-1}):	3100
- EC_{50} 72 hr. algae (mg.l^{-1}):	3800
12.2 Persistence and degradability:	Not specified (not relevant for inorganic substances)
12.3 Bioaccumulative potential:	Not specified
12.4 Mobility in soil:	Not specified
12.5 Results of PBT and vPvBassessment:	Substance is not classified as PBT or vPvB.
12.6 Other adverse effects:	Not specified

13: Disposal considerations

13.1 Waste treatment methods:

If recycling or reuse is not practical then the product must be disposed of by authorized personnel in accordance with local, state or national regulations. Never dispose by flushing into the drainage! Waste former is responsible for its sorting and disposal.

Special safety precaution for recommended waste treatment:

Preferably dispose in independent container. Do not dispose of with acids.

Packaging:

If recycling or reuse is not practical then packaging must be disposed of by authorized personnel in accordance with local, state or national regulations. Clean packaging with water and dispose of washings in accordance to local regulations. Packaging can be passed to a packaging return system after the cleaning.

Legal waste regulations:

Directive 2008/98/ES

National or regional provisions may be in force !

14: Transport information

14.1 UN number	Not applicable (not classified as hazardous for transportation)
14.2 UN proper shipping name	Not applicable (not classified as hazardous for transportation)
14.3 Transport hazard class(es)	Not applicable (not classified as hazardous for transportation)
14.4 Packing group	Not applicable (not classified as hazardous for transportation)
14.5. Environmental hazards	Not applicable (not classified as hazardous for transportation)
14.6. Special precautions for user	Not applicable (not classified as hazardous for transportation)
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable (not classified as hazardous for transportation)

15: Regulatory Information

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


Warning

H 319	Causes serious eye irritation.
P 264	Wash ... thoroughly after handling.
P 280	Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P337 + P 313	If eye irritation persists: Get medical advice/attention.

15.2 Chemical Safety Assessment:

Chemical safety Report (CSR) has been carried out for the substance.

National legislation:

Regulation (EC) No. 1907 / 2006 / ES, REACH
Regulation (EC) No. 1272 / 2008 / ES, CLP

National laws or provisions may be in force !

Canada

WHMIS (Canada) : Class D-2B: Material causing other toxic effects (Toxic).

16: Other information

Changes made in Safety Data Sheet in terms of revision:

Revision of Safety data sheet in terms of avoidance of Directive 67/548/EHS.

Key or explanation for abbreviations:

Eye Irrit. 2	Serious damage of eye/eye irritations, category 2
DNEL	Derived No Effect Level (derived concentration of substance, at which no unfavourable effects occure)
PNEC	Predicted No Effect Concentration (prediction of substance concentration, at which no unfavourable effects occure)
PEL	Acceptable exposure limit, long-term (8 hours)
CSR	Chemical Safety Report

Important literature references and data sources:
CSR, elaborated in terms of registration process in accordance with REACH regulation, special literature.

Training instructions:
According to Safety Data Sheet.

Recommended restrictions of use:
Not specified

ANNEX 1 - EXPOSURE SCENARIOS

Other :
The information contained herein were processed and compiled in accordance with the latest state-of-the-art. Although having been compiled in an utmost good faith, they do not deliver or guarantee any of the product properties, thus they cannot constitute an official base for any contract or legal relation. Various factors may affect the properties under certain conditions. It is the user sole responsibility to assess and consider the accuracy and veracity of the above-indicated information in particular application and/or environment.