

Issuing Date 22-May-2024

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Revision Number 3

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

1.1. Product identifier

Product Code 10035-04-8
Product Name Calcium chloride dihydrate

Other means of identification

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.

EC No (EU Index No) 600-075-5
CAS Number 10035-04-8
Chemical Name Calcium dichloride dihydrate
Synonyms Calcium chloride 2-hydrate
Pure substance/mixture Substance
Formula $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$
Molecular Weight 147.02 g/mol

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

Recommended Use Laboratory chemicals, Biopharma ingredient, Pharma Excipients
Uses advised against Do not use where contact with food or drinking water is possible

1.3. Details of the supplier of the safety data sheet

Manufacturer

Aceto Pharma (India) Private Limited 184-186/P, Vill: Chacharwadi Vasna, Sarkhej-Bavla Highway, Tal-Sanand, Dist-Ahmedabad-382110, Gujarat, India. Web: www.actylislab.comE-Mail Address: safety.amd@actylis.com; qa.amd@actylis.com

1.4. Emergency telephone number

Emergency telephone India: 02717 616 717

Emergency telephone - §45 - (EC)1272/2008
Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Serious eye damage/eye irritation	Category 2 - (H319)
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2.2. Label elements



Signal word

Warning

Hazard statements

H319 - Causes serious eye irritation.

Precautionary Statements - EU (§28, 1272/2008)

P264 - Wash face, hands and any exposed skin thoroughly after handling.

P280 - Wear eye protection/ face protection.

P337 + P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No information available.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Calcium chloride dihydrate	-	-

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Calcium chloride dihydrate	-

SECTION 3: Composition/information on ingredients

3.1 Substances

The product contains no substances which at their given concentration, are considered to be hazardous to health

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Calcium chloride dihydrate 10035-04-8	>95	No data available	600-075-5	Eye Irrit. 2 (H319)	-	-	-

Full text of H- and EUH-phrases: see section 16Acute Toxicity Estimate

No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Calcium chloride dihydrate 10035-04-8	1000	5000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures**4.1. Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth.

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

Symptoms	No information available.
Effects of Exposure	See Section 11 for additional Toxicological Information.

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

Note to physicians	Treat symptomatically.
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SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Non-combustible, substance itself does not burn but may decompose upon heating to produce corrosive and/or toxic fumes.
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Hazardous Combustion Products Hydrogen chloride gas.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Use personal protection equipment. Ensure adequate ventilation. Do not ingest. If swallowed then seek immediate medical assistance.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in a dry area at ambient temperature away from potential sources of heat, open flames, sunlight or other chemicals.

7.3. Specific end use(s)

Risk Management Measures The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Calcium chloride dihydrate 10035-04-8	-	TWA: 5 mg/m ³ Ceiling: 4 mg/m ³	-	-	-
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Calcium chloride dihydrate 10035-04-8	-	-	-	TWA: 2 mg/m ³	-
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-
Chemical name	Sweden		Switzerland		United Kingdom
Calcium chloride dihydrate 10035-04-8	-		-		-

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Bulgaria	Croatia	Czech Republic
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-
Chemical name	Denmark	Finland	France	Germany DFG	Germany TRGS
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-
Chemical name	Hungary	Ireland	Italy MDLPS	Italy AIDII	
Calcium chloride dihydrate 10035-04-8	-	-	-	-	
Chemical name	Latvia	Luxembourg	Romania	Slovakia	
Calcium chloride dihydrate 10035-04-8	-	-	-	-	
Chemical name	Slovenia	Spain	Switzerland	United Kingdom	
Calcium chloride dihydrate 10035-04-8	-	-	-	-	

Derived No Effect Level (DNEL) - Workers No information available

Chemical name	Oral	Dermal	Inhalation
Calcium chloride dihydrate 10035-04-8	-	-	-

Derived No Effect Level (DNEL) - General Public No information available.

Chemical name	Oral	Dermal	Inhalation
Calcium chloride dihydrate 10035-04-8	-	-	-

Chemical name	Oral	Dermal	Inhalation
Calcium chloride dihydrate - 10035-04-8	-	-	-

Predicted No Effect Concentration (PNEC) No information available.

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Calcium chloride dihydrate 10035-04-8	-	-	-	-	-

8.2. Exposure controls

Engineering controls Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face protection Goggles.

Skin and body protection Apron. Antistatic boots.

Respiratory protection Use appropriate respiratory protection.
Particulates filter conforming to EN 143.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls Prevent product from entering drains. Avoid creating dust.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline White
Color No information available
Odor Odorless.
Odor Threshold No information available

Property	Values	Remarks • Method
Melting point / Freezing point	176 °C	None known

Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Flash Point	No data available	None known
Autoignition temperature °C	No data available	None known
Decomposition temperature		None known
pH	4.5-6.5 100 g/l aq. Sol	None known
pH (as aqueous solution)	No data available	None known
Kinematic Viscosity	No data available	None known
Dynamic Viscosity	No Data Available	None known
Water solubility	Soluble in water 147 g/l at 20 °C completely soluble	None known
Solubility in other solvents	No information available	None known
Partition coefficient: n-octanol/water	No data available	None known
Vapor Pressure	0.01 hPa at 20 °C	None known
Relative density	0.830	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapor Density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

Molecular Weight 147.02 g/mol

9.2.1. Information with regard to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity No information available.

10.2. Chemical stability

Stability Hygroscopic.

Explosion Data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid dust formation.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous Decomposition Products Hydrogen chloride gas.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Irritating to eyes.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity**Numerical measures of toxicity**

No information available

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	99,999.00 mg/kg
ATEmix (dermal)	99,999.00 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-vapor)	99,999.00 mg/l
ATEmix (inhalation-dust/mist)	99,999.00 mg/l

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Calcium chloride dihydrate	= 2300 mg/kg (Rat)	> 5000 mg/kg (Rabbit)	Not listed

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Chemical name	European Union
Calcium chloride dihydrate	-

Carcinogenicity No information available.

Chemical name	European Union
Calcium chloride dihydrate	-

Reproductive toxicity No information available.

Chemical name	European Union
Calcium chloride dihydrate	-

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other Adverse Effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Calcium chloride dihydrate	EC50 - Pseudokirchneriella subcapitata - 2,900 mg/l - 72 h	Static test LC50 - Pimephales promelas (fathead minnow) - 4,630 mg/l - 96 h	-	Static test EC50 - Daphnia magna (Water flea) - 2,400 mg/l - 48 h

12.2. Persistence and degradability

Persistence/Degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Chemical name	Partition coefficient
Calcium chloride dihydrate	-

12.4. Mobility in soil

Mobility in Soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment UN.

Chemical name	PBT and vPvB assessment
Calcium chloride dihydrate	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

- 14.1. UN number or ID number Not regulated
- 14.2. UN proper shipping name Not regulated
- 14.3. Transport hazard class(es) Not regulated
- 14.4. Packing group Not regulated
- 14.5. Environmental hazard Not applicable
- 14.6. Special precautions for user
Special Provisions None

IMDG

- 14.1. UN number or ID number Not regulated
- 14.2. UN proper shipping name Not regulated
- 14.3. Transport hazard class(es) Not regulated
- 14.4. Packing Group Not regulated
- 14.5. Environmental hazard Not applicable
- 14.6. Special precautions for user
Special Provisions None
- 14.7. Maritime transport in bulk according to IMO instruments No information available

RID

- 14.1. UN-No Not regulated
- 14.2. UN proper shipping name Not regulated
- 14.3. Transport hazard class(es) Not regulated
- 14.4. Packing Group Not regulated
- 14.5. Environmental hazard Not applicable
- 14.6. Special precautions for user
Special Provisions None

ADR

- 14.1. UN number or ID number Not regulated
- 14.2. UN proper shipping name Not regulated
- 14.3. Transport hazard class(es) Not regulated
- 14.4. Packing Group Not regulated

14.5. Environmental hazard Not applicable

14.6. Special precautions for user

Special Provisions None

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Chemical name	French RG number
Calcium chloride dihydrate - 10035-04-8	-

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Calcium chloride dihydrate	-	-	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Calcium chloride dihydrate - 10035-04-8	75.	-

Persistent Organic Pollutants

Not applicable

Chemical name	Persistent Organic Pollutants per (EC) 2019/1021 - Annex Number
Calcium chloride dihydrate - 10035-04-8	-

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Calcium chloride dihydrate - 10035-04-8	-

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Calcium chloride dihydrate - 10035-04-8	-	-

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Ozone depletion potential (ODP)	Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Calcium chloride dihydrate - 10035-04-8	-	-

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Calcium chloride dihydrate - 10035-04-8	-

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Calcium chloride dihydrate - 10035-04-8	-

Chemical name	EU - Water Framework Directive (2000/60/EC)
Calcium chloride dihydrate - 10035-04-8	-

Chemical name	EU - Environmental Quality Standards (2008/105/EC)
Calcium chloride dihydrate - 10035-04-8	-

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Does not comply
Japan (ENCS)	Complies
Inventory of Existing Chemical Substances in China	Complies
Korea (KECL)	Complies
Philippines (PICCS)	Complies
AIIC	Complies
NZIoC	Complies

- **TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AIIC - Australian Inventory of Industrial Chemicals
NZIoC - New Zealand Inventory of Chemicals

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms****Legend**

SVHC: Substances of Very High Concern for Authorization:
PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances
vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
+	Sensitizers		

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method

Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 Environmental Protection Agency
 Acute Exposure Guideline Level(s) (AEGl(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 National Institute of Technology and Evaluation (NITE)
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Library of Medicine's PubMed database (NLM PUBMED)
 U.S. National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program
 Organization for Economic Co-operation and Development Screening Information Data Set
 World Health Organization

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This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet