(6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE

Safety Data Sheet dated 5.23.2017 version 8

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

1.1. Product identifier

Identification of the substance:

(6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE

Trade name: (6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE, CONFORMS TO LEVOLEUCOVORIN CALCIUM PENTAHYDRATE

Code: MSDS1005

CAS number: 80433-71-2

Registration Number N/A

THIS MSDS REFERS TO (including impurities): (6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE, CONFORMS TO LEVOLEUCOVORIN CALCIUM PENTAHYDRATE, (6S)-CALCIUM FOLINATE/CALCIUM LEVOFOLINATE EP

(6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE, (6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE WS, AND:

10-FORMYLFOLIC ACID

P-AMINOBENZOYLGLUTAMIC ACID

5,10-DIFORMYLTETRAHYDROFOLIC ACID

FOLIC ACID

5-FORMYLTETRAHYDROPTEROIC ACID

10-FORMYLDIHYDROFOLIC ACID

7,8-DIHYDROFOLIC ACID

(6R)-FOLINIC ACID

CHEMICAL NAME: (6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE

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

Recommended use: Pharmaceutical active ingredients.

Uses advised against: All uses not listed in recommended use.

1.3. Details of the supplier of the safety data sheet

Company: Cerbios-Pharma SA

Via Figino 6, 6917 Barbengo/Lugano, SWITZERLAND

Phone: +41 91 985 63 11

Fax: +41 91 985 63 25

1.4. Emergency telephone number

Toxicological Information Center: +41 (0)44 251 51 51 (Short number: 145)

Cerbios-Pharma SA (Office hours): +41 (0)91 985 63 11

Cerbios Emergency Number (24h): +41 (0)79 253 67 78

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) n. 1272/2008 (CLP)

No specific hazards are encountered under normal product use.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

N/A

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

No PBT Ingredients are present

Other Hazards: No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance Identifications: (6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE

Formula: C20H21N7O7Ca

Synonymous: Calcium N-(p-((((6S)-2-amino-5-formyl-5,6,7,8-tetrahydro-4-hydroxy-6- pteridinyl) methyl) amino) benzoyl)-L-glutamate

(6S)-Folinic Acid Calcium salt

(6S)-5-Formyl-5,6,7,8-tetrahydro-pteroylglutamic acid Calcium salt

l-Leucovorin

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Wash immediately with water.

In case of Ingestion:

Do not induce vomiting, get medical attention showing the SDS and label hazardous.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

N.A.

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

N.A.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.
Remove persons to safety.
See protective measures under point 7 and 8.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
Retain contaminated washing water and dispose it.
In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Suitable material for taking up: absorbing material, organic, sand
Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhaltion of vapours and mists.
Don't use empty container before they have been cleaned.
Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
Contamined clothing should be changed before entering eating areas.
Do not eat or drink while working.
See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Store at 2 - 8 °C under vacuum, protected from light. Hygroscopic material.

Incompatible materials:

Avoid strong oxidizing agents.

Instructions as regards storage premises:

7.3. Specific end use(s)

Recommendation(s)

-

Adequately ventilated premises.

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL Type	Country	Ceiling	Long Term µg/m3	Long Term ppm	Short Term µg/m3	Short Term ppm	Behaviour	Note
IOEL			124,000					Category 2 SafeBridge

8.2. Exposure controls

Eye protection:

Wear protective eyeglasses (EN166).

Protection for skin:

Overall

Protection for hands:

Not needed for normal use.

Respiratory protection:

Dust mask.

Environmental exposure controls:

Ensure proper ventilation.

Appropriate engineering controls:
N.A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State Solid
Appearance and colour: Powder whitish
Odour: odourless
Odour threshold: N.A.
pH: 8.00
Melting point / freezing point: N.A.
Initial boiling point and boiling range: N.A.
Flash point: N.A.
Evaporation rate: N.A.
Upper/lower flammability or explosive limits: N.A.
Vapour density: N.A.
Vapour pressure: N.A.
Relative density: N.A.
Solubility in water: Slightly soluble ~ 5 g / liter in water at 25 °C
Solubility: N.A.
Partition coefficient (n-octanol/water): N.A.
Auto-ignition temperature: N.A.
Decomposition temperature: 200.00 °C
Viscosity: N.A.
Explosive properties: N.A.
Oxidizing properties: N.A.
Solid/gas flammability: N.A.
Volatile Organic compounds - VOCs = N.A.

9.2. Other information

Substance Groups relevant properties N.A.
Miscibility: N.A.
Conductivity: N.A.

SECTION 10: Stability and reactivity

10.1. Reactivity

React with oxidising agents

10.2. Chemical stability

Stable at 2 - 8 °C.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Light and air. Hygroscopic material.

10.5. Incompatible materials

Avoid strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products are carbon monoxide, carbon dioxide and nitrogen oxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological Information:

Not classified as dangerous.; Not expected to cause significant effects.; May cause mechanical irritation to the eyes; may cause mild respiratory tract irritation due to dust.

Toxicological Information of the Substance

(6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE	f) carcinogenicity	Carcinogenicity - Long term studies have not been conducted to evaluate the carcinogenic potential. The substance has not been listed as carcinogen by NTP, IARC or OSHA.	
	g) reproductive toxicity	Reproductive Toxicity - No data available for the product	
	e) germ cell mutagenicity	Mutagenesis Generic Bacteria - No data available for the product	
	a) acute toxicity	LD50 Rat = 370,00000 mg/kg - iv	iv
		LD50 Mouse = 315,00000 mg/kg - iv	iv

If not differently specified, the information required in Regulation (EU)2015/830 listed below must be considered as N.A.

a) acute toxicity
b) skin corrosion/irritation
c) serious eye damage/irritation
d) respiratory or skin sensitisation
e) germ cell mutagenicity
f) carcinogenicity
g) reproductive toxicity
h) STOT-single exposure
i) STOT-repeated exposure
j) aspiration hazard

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

Eco-Toxicological Information:

Not expected to be harmful to aquatic plants and animal life.

List of Eco-Toxicological properties of the product

No Data Available

12.2. Persistence and degradability

No persisting influence on the environment to be expected.

12.3. Bioaccumulative potential

Bioaccumulation

Not bioaccumulative

Low

12.4. Mobility in soil

Mobility in soil

Not mobile

Low mobility in the ground

12.5. Results of PBT and vPvB assessment

No PBT Ingredients are present

12.6. Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

14.1. UN number

N.A.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

N.A.

14.4. Packing group

N.A.

14.5. Environmental hazards

N.A.

14.6. Special precautions for user

N.A.

Road and Rail (ADR-RID):

ADR exempt: Yes

N.A.

Air (IATA):

N.A.

Sea (IMDG):

N.A.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

N.A.

SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU)2015/830

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product: None

Restrictions related to the substances contained: None

Provisions related to directive EU 2012/18 (Seveso III):

N.A.

German Water Hazard Class.

Class 1: slightly hazardous for water.

SVHC Substances:

No Data Available

15.2. Chemical safety assessment

Chemical Safety Assessment: No

SECTION 16: Other information

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

Legend to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ATE: Acute Toxicity Estimate

BCF: Biological Concentration Factor

BEI: Biological Exposure Index

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstracts Service (division of the American Chemical Society).

CAV: Poison Center

CE: European Community

CLP: Classification, Labeling, Packaging.

CMR: Carcinogenic, Mutagenic and Reprotoxic

COD: Chemical Oxygen Demand

COV: Volatile Organic Compound

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DMEL: Derived Minimal Effect Level

DNEL: Derived No Effect Level.

DPD: Dangerous Preparations Directive

DSD: Dangerous Substances Directive

EC50: Half Maximal Effective Concentration

ECHA: European Chemicals Agency

EINECS: European Inventory of Existing Commercial Chemical Substances.

ES: Exposure Scenario

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association.

IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).

IC50: half maximal inhibitory concentration

ICAO: International Civil Aviation Organization.

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).

IMDG: International Maritime Code for Dangerous Goods.

INCI: International Nomenclature of Cosmetic Ingredients.

IRCCS: Scientific Institute for Research, Hospitalization and Health Care

KAFH: Keep away from heat

KSt: Explosion coefficient.
LC50: Lethal concentration, for 50 percent of test population.
LD50: Lethal dose, for 50 percent of test population.
LDLo: Leathal Dose Low
N.A.: Not Applicable
N/A: Not Applicable
N/D: Not defined/ Not available
NA: Not available
NEN1: ND: NEN1: ND
NEN2: ND: NEN2: ND
NIOSH: National Institute for Occupational Safety and Health
NOAEL: No Observed Adverse Effect Level
OSHA: Occupational Safety and Health Administration.
PBT: Persistent, Bioaccumulative and Toxic
PGK: Packaging Instruction
PNEC: Predicted No Effect Concentration.
PSG: Passengers
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TWATLV: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
vPvB: Very Persistent, Very Bioaccumulative.
WGK: German Water Hazard Class.