

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Codeine phosphate hemihydrate Codeini phosphas hemihydricus Codeïnefosfaat hemihydraat Codeine (phosphate de) hemihydrate Codeinphosphat - Hemihydrat
N° CAS:	41444-62-6
N° EC:	639-473-9

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 3	H301
Resp. Sens. 1	H334
Skin Sens. 1	H317
Repr. 2	H361
STOT SE 3	H336

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

Hazard statements:

H301	Toxic if swallowed.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H361	Suspected of damaging fertility or the unborn child.
H336	May cause drowsiness or dizziness.

Precautionary statements:

P284	In case of inadequate ventilation wear respiratory protection.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P321	Specific treatment (see on this label)
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Codeine phosphate hemihydrate
IUPAC name:	4,5 α -Epoxy-3-methoxy-17-methyl-7,8-didehydromorphinan-6 α -ol phosphate hemihydrate.
Synonyms:	Codeine phosphate hydrate UNII-GSL05Y1MN6
N° CAS:	41444-62-6
N° EC:	200-137-8
Molecular Formula:	C ₁₈ H ₂₄ NO ₇ P, ½H ₂ O
Content:	99.0 per cent to 101.0 per cent (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	When in doubt or if symptoms are observed, get medical advice.
After inhalation:	Remove the affected person from exposure site and provide him/her with enough of fresh air. Apply artificial respiration and get the medical attention, if needed.
After skin contact:	Remove contaminated clothing and/or shoes. Wash the affected skin with a soap and large amounts of water. Get the medical attention, if needed.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

After eye contact:	Rinse eyes with large amounts of water lifting upper and lower lids. Get the medical attention.
After ingestion:	Contact a physician or the local Toxicology Information Centre. Put the affected person to the stabilized position. Get the medical attention. In case of the substance ingestion consider a stomach irrigation.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Regular water spray, dry chemical powder, carbon dioxide or foam extinguishers.
Unsuitable extinguishing media:	High-pressure water streams bringing a scatter of the spilled material should be avoided.

5.2 Special hazards arising from the substance/mixture

When heated to decomposition the material emits toxic fumes (nitrogen oxides).

5.3 Advice for firefighters

Surrounding fires:	Avoid material scattering, be aware of potential risk of dust ignition from mechanical equipment, keep away ignition sources.
Protection against fire:	Respirator and protective clothing
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Isolate in case of greater releases the contaminated area with no entry of unnecessary persons. Keep away ignition sources.

For emergency responders

Emergency responders performing the contaminated area sanitation has to be provided with respirators, gloves, and protective clothing. Isolate in case of greater releases the contaminated area with no entry of unnecessary persons. Keep away ignition sources.

6.2 Environmental precautions

Avoid an escape of a release to sewers. Using protective clothing, respirator, and gloves, confine a spilled material and collect it in an emergency container.

6.3 Methods and material for containment and cleaning up

For containment: Collect in closed and suitable containers for disposal. Treat the recovered material as prescribed in the section on waste disposal (section 13).

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

For cleaning up: Take up carefully when dry.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid a direct contact with the substance. Prevent from a dust inhalation, skin direct contact, and direct eye affection. Remove contaminated clothing.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in a tightly closed container.
Conditions for safe storage, including any incompatibilities:	Store in a dry and well-ventilated place.
Storage – away from:	Protected from light. Keep away from heat.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

The substance is allowed to be treated in explosion-proof fume hoods or in ventilated rooms only.

Individual protection measures

Eye/face protection:	Wear appropriate safety washable goggles.
Skin protection:	Wear appropriate chemical resistant clothing.
Hand protection:	Wear appropriate chemical resistant gloves.
Respiratory protection:	Provide exhaust ventilation; apply a respirator. At higher exposure the use of an approved dust mask is recommended.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

Appearance:	White or almost white, crystalline powder or small, colourless crystals.
Odour:	Odourless
Odour threshold:	Not available.
pH:	4.0 to 5.0
Melting/freezing point:	Not available.
Initial boiling point:	462 °C at 760 mmHg
Boiling range:	Not available.
Flash point:	233.2 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble or very slightly soluble in ethanol (96 per cent)
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The substance is stable under the normal atmospheric conditions.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Oxidising substances.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

10.6 Hazardous decomposition products

Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 85 mg/kg Oral LD50 (mouse): 237 mg/kg
Skin corrosion/irritation:	Irritant.
Serious eye damage/irritation:	Irritant.
Respiratory/skin sensitisation:	Not sensitising.
Germ cell mutagenicity:	No indications of human germ cell mutagenicity exist.
Carcinogenicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Reproductive toxicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Prolonged or repeated contact with skin or mucous membrane results in irritation symptoms such as redness, blistering, dermatitis, etc.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause an allergic skin reaction.
Skin contact:	Prolonged or repeated contact with skin results in irritation symptoms such as redness, blistering, dermatitis, etc.
Inhalation:	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Prolonged or repeated contact with mucous membrane results in irritation symptoms such as redness, blistering, dermatitis, etc.
Ingestion:	Toxic if swallowed. Prolonged or repeated contact with skin results in irritation symptoms such as redness, blistering, dermatitis, etc.
Aspiration:	Prolonged or repeated contact with mucous membrane results in irritation symptoms such as redness, blistering, dermatitis, etc.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Harmless to aquatic organisms up to the tested concentration.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CODEINI PHOSPHAS HEMIHYDRICUS

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No indication of bioaccumulative potential.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT and vPvB criteria of REACH, Annex XIII.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Methods of the substance/medicinal product disposal:

Incineration in the licensed incinerator.

Methods of the contaminated container disposal:

Combustible primary package should be incinerated in the licensed incinerator. Non-combustible contaminated primary packages should be passed for the disposal to a company authorized for hazardous waste disposal.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 1544
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Alkaloid salts N.O.S. (Codeine phosphate hemihydrate)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), No.
IATA/ICAO (Air) :

14.6 Special precautions for user

Hazard identification number: 60

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

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

Not available.

14.8 Additional transport information

ADR Classification code: T2

ADR/IMDG Limited quantities (LQ): 5L

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R25 Toxic if swallowed.

R60 May impair fertility.

R61 May cause harm to the unborn child.

R67 Vapours may cause drowsiness and dizziness.

Safety phrases:

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S38 In case of insufficient ventilation, wear suitable respiratory equipment.

S46 If swallowed, seek medical advice immediately and show this container label.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 17/07/2024

Revision: XX/XX/XXXX

Version: 00



CODEINI PHOSPHAS HEMIHYDRICUS

vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization 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 Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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