

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/10

DEXAMETHASONI NATRII PHOSPHAS

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



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

1.1 Product identifier

Product name:	Dexamethasone sodium phosphate Dexamethasoni natrii phosphas Dexamethasonnatriumfosfaat Dexaméthasone (phosphate sodique de) Dexamehtasondihydrogenphosphat-Dinatrium
N° CAS:	2392-39-4
N° EC:	219-243-0

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
------------------	--

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. 4	H302
Acute Tox. 4	H332
Carc. 2	H351
Repr. 1B	H360
Repr. 2	H361
STOT RE 2	H373

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 2/10

DEXAMETHASONI NATRII PHOSPHAS

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



Hazard statements:

H302	Harmful if swallowed.
H332	Harmful if inhaled.
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.
H361	Suspected of damaging fertility or the unborn child.
H373	May cause damage to organs.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P281	Use personal protective equipment as required.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P304+P312	IF INHALED: Call a POISON CENTER/doctor if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER/doctor if you feel unwell.
P314	Get medical advice/attention if you feel unwell.
P330	Rinse mouth.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local regulations.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dexamethasone sodium phosphate
IUPAC name:	9-Fluoro-11 β ,17-dihydroxy-16 α -methyl-3,20-dioxopregna-1,4-dien-21-yl disodium phosphate
Synonyms:	Dexamethasone 21-(disodium phosphate) Dalalone
N° CAS:	2392-39-4

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/10

DEXAMETHASONI NATRII PHOSPHAS

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



N° EC: 219-243-0
Molecular Formula: $C_{22}H_{28}FNa_2O_8P$
Content: 97.0 per cent to 102.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.
After skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.
After ingestion: Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

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

In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray. Carbon dioxide. Dry powder.
Unsuitable extinguishing media: Do not use a heavy water stream.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Use water spray or fog for cooling exposed containers.
Protection against fire: Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous combustion products: Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove ignition sources. Evacuate area.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/10

DEXAMETHASONI NATRII PHOSPHAS

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

For emergency responders

Remove ignition sources. Evacuate area.

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing.
Technical protective measures:	Material should be handled in a laboratory hood whenever possible.
Handling:	Handle in accordance with good industrial hygiene and safety procedures.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Protected from light. All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see section 10.

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

Provide local exhaust or general room ventilation. Material should be handled in a laboratory hood whenever possible.

Individual protection measures

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/10

DEXAMETHASONI NATRII PHOSPHAS

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



Eye/face protection:	Chemical goggles or safety glasses.
Skin protection:	Wear suitable protective clothing.
Hand protection:	Wear suitable gloves resistant to chemical penetration.
Respiratory protection:	Wear approved mask. (P3) In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards:	Not determined.
Environmental exposure control	
Not available.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, very hygroscopic powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	7.5 - 10.5 (10g/l)
Melting/freezing point:	233 – 235 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
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 in ethanol (96 per cent). Practically insoluble in methylene chloride.
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

Material Safety Data Sheet

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

DEXAMETHASONI NATRII PHOSPHAS

EN

FORM-06-14-01 (V00)

Page 6/10

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



Molecular weight: 516.4

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

None under normal conditions. Hazardous polymerization will not occur.

10.4 Conditions to avoid

Moisture. Light.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

Carbon dioxide. Phosphorous oxide. Hydrogen fluoride. Carbon monoxide. When heated to decomposition, emits dangerous fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rat): 1600-2000 mg/kg Endocrine disorders. Pharmacologically active at low dose. Immune system suppression. May produce irregular heartbeat and nervous symptoms. Oedema. Gastrointestinal disorders.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Chronic toxicity : Endocrine disorders. RTECS nr: TU4056000 (See actual entry in RTECS for complete information.)

11.2 Additional information on potential adverse human health effects and symptoms

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/10

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



DEXAMETHASONI NATRII PHOSPHAS

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

LC₅₀ – 96 hour - fish: > 100 mg/l

12.2 Persistence and degradability

Biodegradation: 49 %

Potentially biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/10

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



DEXAMETHASONI NATRII PHOSPHAS

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

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

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R20/22 Harmful by inhalation and if swallowed.
R48 Danger of serious damage to health by prolonged exposure.
R60 May impair fertility.
R61 May cause harm to the unborn child.
R62 Possible risk of impaired fertility.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.
S20/21 When using do not eat, drink or smoke
S23 Do not breathe dust/fume/gas/mist/vapours/spray.
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S51 Use only in well-ventilated areas.
S53 Avoid exposure - obtain special instructions before use.
S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/10

DEXAMETHASONI NATRII PHOSPHAS

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



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)
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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

Material Safety Data Sheet

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

DEXAMETHASONI NATRII PHOSPHAS

EN

FORM-06-14-01 (V00)

Page 10/10

Publication: 07/10/2022

Revision: 24/07/2024

Version: 01



FAC SECUNDUM ARTEM NV

info@magis-pharma.be