

Prednisolone sodium phosphate

Safety Data Sheet

258938

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Date of issue: 19/06/2012 Revision date 05/03/2020

Supersedes 28/03/2019

Version: 3.1

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

1.1. Product identifier

Product form	: Substance
Substance name	: Prednisolone sodium phosphate
IUPAC name	: 11 β ,17-Dihydroxy-3,20-dioxopregna-1,4-dien-21-yl disodium phosphate
EC-No.	: 204-722-9
CAS-No.	: 125-02-0
Product code	: 258938
Formula	: C ₂₁ H ₂₇ Na ₂ O ₈ P
Product group	: Raw material

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

1.2.1. Relevant identified uses

Main use category	: Pharmaceutical industry
Use of the substance/mixture	: Active ingredient for the preparation of pharmaceuticals
Function or use category	: Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number	: Supplier contact information: +31(0)23-5319093 (M-F 09:00-17:00) +31(0)6-30109355 (outside office hours)
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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Reproductive toxicity, Category 2 H361

Specific target organ toxicity — Repeated exposure, Category 2 H373

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display/Extra classification(s) to display

Hazard pictograms (CLP)

:



GHS08

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H361 - Suspected of damaging fertility or the unborn child.
H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P314 - Get medical advice/attention if you feel unwell.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prednisolone sodium phosphate	(CAS-No.) 125-02-0 (EC-No.) 204-722-9	96 - 103	Repr. 2, H361 STOT RE 2, H373

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Remove victim to fresh air Call a POISON CENTER/doctor if you feel unwell.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Never give anything by mouth to an unconscious person Seek medical advice.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No fire hazard.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: On burning: release of toxic and corrosive gases/vapours (carbon monoxide - carbon dioxide).

5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Ensure adequate air ventilation. Avoid raising dust. Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Wear recommended personal protective equipment.
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6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. Hose down area with water.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area
Keep container tightly closed.
Protect from sunlight.
Protect from moisture.

Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Dust/aerosol mask with filter type P3. Safety glasses. Gloves.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

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Dustmask with filtertype P3



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 484.4 g/mol
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: 7.5 - 9 (5% solution in water)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Freely soluble in water Practically insoluble in alcohol.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Material is hygroscopic.

10.3. Possibility of hazardous reactions

No additional information available

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10.4. Conditions to avoid

High temperature
Light (daylight)
Moisture.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide
Carbon monoxide
On heating/burning: release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Prednisolone sodium phosphate (125-02-0)	
LD50 oral	> 2000 mg/kg mouse

Skin corrosion/irritation : Not classified
pH: 7.5 - 9 (5% solution in water)

Serious eye damage/irritation : Not classified
pH: 7.5 - 9 (5% solution in water)

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

STOT-single exposure : Not classified

STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Prednisolone sodium phosphate (125-02-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Prednisolone sodium phosphate (125-02-0)	
Bioaccumulative potential	No bioaccumulation data available.

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12.4. Mobility in soil

Prednisolone sodium phosphate (125-02-0)	
Ecology - soil	There are no available data for a classification.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Avoid release to the environment.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

. Overland transport

No data available

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

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No REACH Annex XVII restrictions

Prednisolone sodium phosphate is not on the REACH Candidate List

Prednisolone sodium phosphate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : EP. Supplier.

Full text of H- and EUH-statements:

Repr. 2	Reproductive toxicity, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H361	Suspected of damaging fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

SDS EU (REACH Annex II) ducheфа nieuwe logo

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