

Hydrocortisone disodium phosphate

Safety Data Sheet

497258

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Issue date: 12/01/2015 Revision date 23/11/2020
Supersedes 28/02/2017

Version: 3.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Hydrocortisone disodium phosphate
IUPAC name	: Pregn-4-ene-3,20-dione, 11,17-dihydroxy-21-(phosphonooxy)-, disodium salt, (11β)-
EC-No.	: 227-843-9
CAS-No.	: 6000-74-4
Product code	: 497258
Formula	: C21H29O8P.2Na
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
Industrial/Professional use spec	: Industrial For professional use only
Use of the substance/mixture	: Pharmaceuticals
Function or use category	: glucocorticoid

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@duchefa.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)

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]

Reproductive toxicity, Category 1A

H360

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]

Hazard pictograms (CLP)

:



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H360 - May damage fertility or the unborn child.

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

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]
Hydrocortisone disodium phosphate	(CAS-No.) 6000-74-4 (EC-No.) 227-843-9	≈ 100	Repr. 1A, H360

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

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First-aid measures general	: Never give anything by mouth to an unconscious person If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Allow affected person to breathe fresh air Allow the victim to rest Seek medical attention immediately.
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 If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse immediately with plenty of water Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth Obtain emergency medical attention.

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

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

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

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂) Phosphorus oxides.
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5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Use self-contained breathing apparatus and chemically protective clothing.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

General measures	: Ensure adequate ventilation.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel. Do not breathe dust.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : If used professionally, requires no special measures.

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Water, humidity, Material is hygroscopic
Keep container closed when not in use.

Storage temperature : 2 - 8 °C

Storage area : Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Hydrocortisone disodium phosphate (6000-74-4)		
EU	IOELV TWA (mg/m ³)	< 1 mg/m ³

8.2. Exposure controls

Appropriate engineering controls:

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

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)

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Respiratory protection:

Dustmask with filtertype P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 486.45 g/mol
Colour	: White to off-white.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
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)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Highly soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: <
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

Stable under normal conditions

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

High temperature

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Direct sunlight

Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids

Strong bases.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂)

Phosphorus oxides

fume.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Irritating. May cause stomach cramps and vomiting

Hydrocortisone disodium phosphate (6000-74-4)	
LD50 oral rat	6100 mg/kg
LD50 oral	3950 mg/kg mouse

Skin corrosion/irritation	: May cause eye, skin and respiratory system irritation
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: May cause eye irritation
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met Inhalation may cause irritation (cough, short breathing, difficulty in breathing)
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met May cause irritation to the respiratory tract
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

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

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12.2. Persistence and degradability

Hydrocortisone disodium phosphate (6000-74-4)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Hydrocortisone disodium phosphate (6000-74-4)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

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

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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

No REACH Annex XVII restrictions

Hydrocortisone disodium phosphate is not on the REACH Candidate List

Hydrocortisone disodium 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:

2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	H351
2.2	Hazard statements (CLP)	Removed	H350
4.1	First-aid measures after skin contact	Modified	
4.3	Other medical advice or treatment	Added	
5.1	Suitable extinguishing media	Modified	
7.1	Precautions for safe handling	Modified	
8.1	IOELV TWA (mg/m ³)	Added	
8.2	Appropriate engineering controls	Added	

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

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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Other information : None.

Full text of H- and EUH-statements:

Repr. 1A	Reproductive toxicity, Category 1A
H360	May damage fertility or the unborn child.

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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.