

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formulation

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

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

#### 1.1 Product identifier

Trade name : Betamethasone Sodium Phosphate Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 1

Long-term (chronic) aquatic hazard, Category 1

H360D: May damage the unborn child.

H372: Causes damage to organs through prolonged or repeated exposure.

H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

Hazard statements : H360D May damage the unborn child.  
H372 Causes damage to organs through prolonged or re-  
peated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protec-  
tion/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/  
attention.  
P391 Collect spillage.

Hazardous components which must be listed on the label:  
betamethasone

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumula-  
tive and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or  
higher.

Ecological information: The substance/mixture does not contain components considered to have  
endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regu-  
lation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to  
have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated  
regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form combustible dust concentrations in air during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland,	>= 0,3 - < 1

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

		Immune system, muscle, thymus gland, Blood, Ad- renal gland) Aquatic Chronic 1; H410 <hr/> M-Factor (Chronic aquatic toxicity): 1.000 <hr/> specific concentra- tion limit STOT RE 1; H372 >= 0,01 % Repr. 1B; H360D >= 0,01 %	
--	--	--	--

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

---

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

Risks : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

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

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : No hazardous combustion products are known

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

---

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

### 8.2 Exposure controls

#### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

#### Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

---

Flammability (solid, gas)	:	May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics Particle size	:	Not applicable

### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form combustible dust concentrations in air during processing, handling or other means.  
Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### Components:

##### betamethasone:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
LD50 (Mouse): > 4.500 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 0,4 mg/l  
Exposure time: 4 h

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

### II

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### betamethasone:

Species : Rabbit  
Result : Mild skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### betamethasone:

Species : Rabbit  
Result : No eye irritation

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### betamethasone:

Exposure routes : Dermal  
Species : Guinea pig  
Result : Weak sensitizer

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### betamethasone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
  
Test Type: Chromosome aberration test in vitro  
Result: positive  
  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

Species: Mouse  
Application Route: Oral  
Result: equivocal

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### **Carcinogenicity**

Not classified based on available information.

### **Reproductive toxicity**

May damage the unborn child.

### **Components:**

#### **betamethasone:**

Effects on foetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0,05 mg/kg body weight  
Result: Fetotoxicity, Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0,42 mg/kg body weight  
Result: Malformations were observed.

Species: Mouse  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

### **Components:**

#### **betamethasone:**

Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland  
Assessment : Causes damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formulation

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

### Repeated dose toxicity

#### Components:

##### betamethasone:

Species : Rabbit  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 10 - 30 d  
Target Organs : Pituitary gland, Immune system, muscle

Species : Rat  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus gland

Species : Mouse  
LOAEL : 0.1 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus gland

Species : Dog  
LOAEL : 0,05 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Target Organs : Blood, thymus gland, Adrenal gland

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### Experience with human exposure

#### Components:

##### betamethasone:

Inhalation : Target Organs: Adrenal gland  
Skin contact : Symptoms: Redness, pruritis, Irritation

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **betamethasone:**

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Americamysis): > 50 mg/l Exposure time: 96 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility  NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,052 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210  NOEC: 0,07 µg/l Exposure time: 219 d Species: Oryzias latipes (Japanese medaka) Method: OECD Test Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 8 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1.000

#### 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

##### Components:

##### **betamethasone:**

Partition coefficient: n-octanol/water	:	log Pow: 2,11
--	---	---------------

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

---

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : UN 3082  
ADR : UN 3082  
RID : UN 3082  
IMDG : UN 3082  
IATA : UN 3082

### 14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019

(betamethasone)  
**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(betamethasone)  
**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(betamethasone)  
**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(betamethasone)  
**IATA** : Environmentally hazardous substance, liquid, n.o.s.  
(betamethasone)

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 9	

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

**ADR**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

**RID**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

**IMDG**  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

**IATA (Cargo)**  
Packing instruction (cargo) : 964

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

aircraft)  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

#### ADR

Environmentally hazardous : yes

#### RID

Environmentally hazardous : yes

#### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75, 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version 3.0      Revision Date: 06.04.2024      SDS Number: 3960915-00013      Date of last issue: 30.09.2023  
Date of first issue: 29.01.2019



determine whether an entry is applicable to the placing on the market or not.

If you intend to use this product as tattoo ink, please contact your vendor.

- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
- Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
- Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### The components of this product are reported in the following inventories:

- AICS : not determined
- DSL : not determined
- IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

- Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

- H330 : Fatal if inhaled.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

H360D : May damage the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Repr. 1B

H360D

### Classification procedure:

Calculation method

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Betamethasone Sodium Phosphate Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	3960915-00013	Date of first issue: 29.01.2019

---

STOT RE 1	H372	Calculation method
Aquatic Chronic 1	H410	Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NO / EN