

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

SECTION 1. IDENTIFICATION

Product name : Betamethasone Solid Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302
Telephone : 1-551-430-6000
Emergency telephone : 1-215-631-6999
E-mail address : EHSSTEWART@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : May form combustible dust concentrations in air.
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

SAFETY DATA SHEET

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Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
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Response:

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	$\geq 20 - < 30$
Aspartame	22839-47-0	$\geq 1 - < 5$
Betamethasone	378-44-9	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

SECTION 4. 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.
- 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.
- Most important symptoms and effects, both acute and delayed : 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.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
6.0	04/06/2024	1832807-00015	Date of first issue: 07/13/2017

Notes to physician : when the potential for exposure exists (see section 8).
: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Do not use a solid water stream as it may scatter and spread fire.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)

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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
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.
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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
6.0	04/06/2024	1832807-00015	Date of first issue: 07/13/2017

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- 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 dust.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety 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.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m ³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m ³ Value type (Form of exposure): TWA (respirable fraction)

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
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	Basis: OSHA Z-3
	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m ³ Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m ³ Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Betamethasone	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

Engineering measures : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
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.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
6.0	04/06/2024	1832807-00015	Date of first issue: 07/13/2017

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye 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.

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air.

Flammability (liquids) : No data available

Upper explosion limit / Upper : No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
6.0	04/06/2024	1832807-00015	Date of first issue: 07/13/2017

flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Minimum explosible dust concentration : 60 - 125 g/m³

Dust deflagration index (Kst) : 16 - 75 m.b./s

Minimum ignition energy : > 10 mJ

Particle characteristics
Particle size : 10 - 220 µm

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form combustible dust concentrations in air.
Can react with strong oxidizing agents.

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

SECTION 11. TOXICOLOGICAL INFORMATION

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: 52.63 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Aspartame:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

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

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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

Components:

Betamethasone:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Betamethasone:

Routes of exposure : Dermal
Species : Guinea pig
Result : Weak sensitizer

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Aspartame:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

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)
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.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Aspartame:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

IARC Group 2B: Possibly carcinogenic to humans
Aspartame 22839-47-0

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child.

Components:

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Aspartame:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Betamethasone:

Effects on fetal 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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

|| exposure.

Repeated dose toxicity

Components:

Cellulose:

|| Species : Rat
|| NOAEL : $\geq 9,000$ mg/kg
|| Application Route : Ingestion
|| Exposure time : 90 Days

Aspartame:

|| Species : Rat
|| NOAEL : $\geq 4,000$ mg/kg
|| Application Route : Ingestion
|| Exposure time : 104 Weeks

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.

Experience with human exposure

Components:

Betamethasone:

|| Inhalation : Target Organs: Adrenal gland

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

|| Skin contact : Symptoms: Redness, pruritis, Irritation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

|| Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Aspartame:

|| Toxicity to fish : LC50 (*Danio rerio* (zebra fish)): > 20 g/l
Exposure time: 96 h

|| Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

|| Toxicity to algae/aquatic plants : ErC50 (*Desmodesmus subspicatus* (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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 (*Pimephales promelas* (fathead minnow)): 0.052 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

NOEC (*Oryzias latipes* (Japanese medaka)): 0.07 µg/l
Exposure time: 219 d
Method: OECD Test Guideline 229

|| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 8 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version 6.0 Revision Date: 04/06/2024 SDS Number: 1832807-00015 Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

II

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Aspartame:

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Aspartame:

Partition coefficient: n-octanol/water : log Pow: 0.07
Remarks: Calculation

Betamethasone:

Partition coefficient: n-octanol/water : log Pow: 2.11

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(betamethasone)
Class : 9
Packing group : III
Labels : 9

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
6.0	04/06/2024	1832807-00015	Date of first issue: 07/13/2017

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Betamethasone)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Betamethasone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Betamethasone)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes(Betamethasone)
Remarks : Above applies only to containers over 119 gallons or 450
liters.
Shipment by ground under DOT is non-regulated; however it
may be shipped per the applicable hazard classification to
facilitate multi-modal transport involving ICAO (IATA) or IMO.

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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
6.0	04/06/2024	1832807-00015	Date of first issue: 07/13/2017

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Lactose	63-42-3
Cellulose	9004-34-6
Polyvinyl pyrrolidone	9003-39-8

California List of Hazardous Substances

Polyvinyl pyrrolidone	9003-39-8
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California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
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The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

Betamethasone Solid Formulation

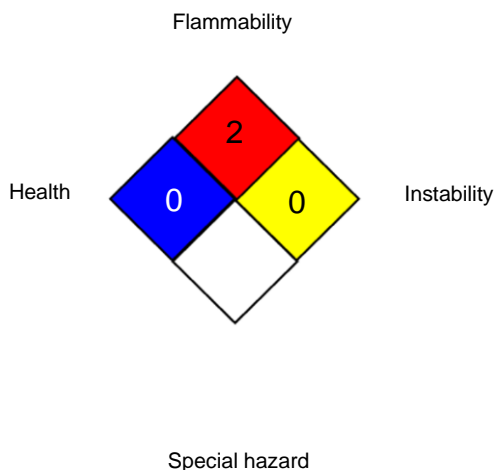
Version
6.0

Revision Date:
04/06/2024

SDS Number:
1832807-00015

Date of last issue: 09/30/2023
Date of first issue: 07/13/2017

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		2
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 Pre-

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

Betamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
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vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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

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

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