

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
Date of first issue: 23.02.2018

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification in accordance with ABNT NBR 14725 Standard**

Long-term (chronic) aquatic hazard : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard Statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**
P273 Avoid release to the environment.

Other hazards which do not result in classification

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Starch	9005-25-8		>= 30 < 50
Dexamethasone	50-02-2	Reproductive toxicity, Category 1B	>= 0,25 < 0,3

Dexamethasone Solid Formulation

Version 4.0	Revision Date: 04.04.2023	SDS Number: 2533226-00011	Date of last issue: 01.10.2022 Date of first issue: 23.02.2018
----------------	------------------------------	------------------------------	---

		Specific target organ toxicity - repeated exposure (Oral) (Adrenal gland, Immune system, thymus gland), Category 2 Long-term (chronic) aquatic hazard, Category 1	
--	--	--	--

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 : 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 when the potential for exposure exists (see section 8).
- Notes to physician : 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 : None known.
- 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.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides

Dexamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
4.0	04.04.2023	2533226-00011	Date of first issue: 23.02.2018

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.
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.
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.

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
 Date of first issue: 23.02.2018

- Keep away from heat and sources of ignition.
 Take precautionary measures against static discharges.
 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.
- Conditions for safe storage : Keep in properly labeled containers.
 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
Dexamethasone	50-02-2	TWA	10 µg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	100 µg/100 cm ²	Internal

- 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.
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
 Minimize open handling.

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves

Dexamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
4.0	04.04.2023	2533226-00011	Date of first issue: 23.02.2018

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.

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 explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
Date of first issue: 23.02.2018

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.

Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:**Starch:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Dexamethasone:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
Date of first issue: 23.02.2018

LD50 (Mouse): > 6.500 mg/kg
Acute toxicity (other routes of administration) : LD50 (Rat): 14 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:**Dexamethasone:**

Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Starch:**

Species : Rabbit
Result : No eye irritation

Dexamethasone:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Starch:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**Starch:**

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

Dexamethasone:

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
 Date of first issue: 23.02.2018

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

Test Type: in vitro test
 Test system: mouse lymphoma cells
 Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse
 Application Route: Oral
 Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Dexamethasone:

Effects on fetal development : Test Type: Development
 Species: Mouse
 Application Route: Subcutaneous
 Developmental Toxicity: LOAEL: 6 mg/kg body weight
 Result: Specific developmental abnormalities., Cleft palate

Species: Rabbit
 Application Route: Intramuscular
 Developmental Toxicity: NOAEL: 0,025 mg/kg body weight
 Result: Specific developmental abnormalities.

Species: Rabbit
 Application Route: Intramuscular
 Developmental Toxicity: LOAEL: >= 0,062 mg/kg body weight
 Result: Specific developmental abnormalities.

Species: Rat
 Application Route: Subcutaneous
 Developmental Toxicity: LOAEL: >= 0,02 mg/kg body weight
 Result: Skeletal and visceral variations ., Retardations.

Reproductive toxicity - Assessment : May damage the unborn child.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

Dexamethasone:

Routes of exposure : Oral
 Target Organs : Adrenal gland, Immune system, thymus gland

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
 Date of first issue: 23.02.2018

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

Repeated dose toxicity

Components:

Starch:

Species : Rat
 NOAEL : ≥ 2.000 mg/kg
 Application Route : Skin contact
 Exposure time : 28 Days
 Method : OECD Test Guideline 410

Dexamethasone:

Species : Rat
 NOAEL : 0,0015 mg/kg
 Application Route : Oral
 Exposure time : 7 d
 Target Organs : Liver
 Remarks : Significant toxicity observed in testing

Species : Rat
 LOAEL : 0,003 mg/kg
 Application Route : Oral
 Exposure time : 90 d
 Target Organs : Blood, Adrenal gland, thymus gland
 Remarks : Significant toxicity observed in testing

Species : Rat
 LOAEL : 0,125 mg/kg
 Application Route : Oral
 Exposure time : 6 Weeks
 Target Organs : Adrenal gland
 Remarks : Significant toxicity observed in testing

Species : Rat
 LOAEL : 0,4 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Immune system
 Remarks : Significant toxicity observed in testing

Species : Dog
 LOAEL : 8 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Immune system
 Remarks : Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
 Date of first issue: 23.02.2018

Experience with human exposure**Components:****Dexamethasone:**

Ingestion : Target Organs: Immune system
 Target Organs: Adrenal gland
 Target Organs: Bone
 Symptoms: muscle weakness

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Dexamethasone:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 56 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,2 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9,2 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,033 mg/l
 Exposure time: 32 d
 Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

Persistence and degradability**Components:****Dexamethasone:**

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 50 %
 Exposure time: 3,54 d

Dexamethasone Solid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 2533226-00011 Date of last issue: 01.10.2022
Date of first issue: 23.02.2018

Method: OECD Test Guideline 314

Bioaccumulative potential**Components:****Dexamethasone:**

Partition coefficient: n-octanol/water : log Pow: 1,83

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**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Dexamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
4.0	04.04.2023	2533226-00011	Date of first issue: 23.02.2018

Brazil. List of chemicals controlled by the Federal Police : Not applicable

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 04.04.2023
Date format : dd.mm.yyyy

Further information

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/>

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 other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; KECl - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No

Dexamethasone Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
4.0	04.04.2023	2533226-00011	Date of first issue: 23.02.2018

1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

BR / Z8