

# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

#### **Section 1: Identification**

**Product identifier** : Dexamethasone Solid Formulation

## Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

### Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

### Section 2: Hazard identification

### Classification of the substance or mixture

Not a hazardous substance or mixture.

### GHS Label elements, including precautionary statements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

### 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.	Concentration (% w/w)	
Starch	9005-25-8	>= 30 -< 50	
Dexamethasone	50-02-2	>= 0.25 -< 0.3	



# **Dexamethasone Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 2.3
 28.09.2024
 2533181-00015
 Date of first issue: 23.02.2018

#### Section 4: First-aid measures

Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

### Section 5: Fire-fighting measures

**Extinguishing media** 

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

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 prod- : Carbon oxides



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

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# Special protective actions for fire-fighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

### Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

**Environmental precautions** 

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

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## Section 7: Handling and storage

## 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.



# **Dexamethasone Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 2.3
 28.09.2024
 2533181-00015
 Date of first issue: 23.02.2018

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 eves.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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.

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, including any incompatibilities

Conditions for safe storage : Keep in properly labelled 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

### Section 8: Exposure controls/personal protection

### **Control parameters**

## **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Starch	9005-25-8	PEL (long term)	10 mg/m3	SG OEL		
		TWA	10 mg/m3	ACGIH		
Dexamethasone	50-02-2	TWA	10 μg/m3 (OEB 3)	Internal		
	Further inform	Further information: Skin				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal		



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

Appropriate engineering control 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 con-

tainment devices). Minimize open handling.

Individual protection measures, such as personal protective equipment (PPE)

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.

Skin protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Section 9: Physical and chemical properties

Appearance : powder

Colour : white

Odour : No data available

Odour 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



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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

Vapour pressure : Not applicable

Relative vapour 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

Auto-ignition 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 characteristics

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 reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.



# **Dexamethasone Solid Formulation**

Version SDS Number: Date of last issue: 06.04.2024 Revision Date: 2533181-00015 2.3 28.09.2024 Date of first issue: 23.02.2018

Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

**Section 11: Toxicological information** 

Information on likely routes of: Inhalation

exposure Skin contact Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Starch:

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

: LD50 (Rabbit): > 2,000 mg/kg Acute dermal toxicity

Dexamethasone:

Acute oral toxicity LD50 (Rat): > 2,000 mg/kg

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



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

### **Components:**

#### Starch:

Test Type : Maximisation Test
Exposure routes : 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:

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

Result: negative

Test Type: in vitro assay

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 foetal develop-

Species: Mouse

ment

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: Specific developmental abnormalities, Cleft palate

Test Type: Development



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

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 - As-

sessment

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:

Exposure routes : Oral

Target Organs : Adrenal gland, Immune system, thymus gland

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



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

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.

## **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**

# **Toxicity**

## **Components:**

### Dexamethasone:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 56 mg/l

aquatic invertebrates Exposure time: 48 h

Method: OECD Test Guideline 202



# **Dexamethasone Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 2.3
 28.09.2024
 2533181-00015
 Date of first issue: 23.02.2018

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 tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

: 1

: 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

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



# **Dexamethasone Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2533181-00015 Date of first issue: 23.02.2018

### Section 13: Disposal considerations

# **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **Section 14: Transport information**

### International Regulations

### **UNRTDG**

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

### **IATA-DGR**

UN/ID No. : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen: Not applicable

ger aircraft)

#### **IMDG-Code**

**UN** number Not applicable UN proper shipping name Not applicable Transport hazard class(es) Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

# Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable



# **Dexamethasone Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 2.3
 28.09.2024
 2533181-00015
 Date of first issue: 23.02.2018

### **Section 15: Regulatory information**

# Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials)

Regulations

Not applicable

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 28.09.2024

**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 Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Toxic Substances.

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

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - 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



# **Dexamethasone Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 2.3
 28.09.2024
 2533181-00015
 Date of first issue: 23.02.2018

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; 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 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.

SG / EN