

## Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

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

**Product identifier** : Dexamethasone (0.085%) 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

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	>= 1 -< 10
Dexamethasone	50-02-2	>= 0.025 -< 0.1

### Section 4: First-aid measures

### **Description of necessary first-aid measures**

If inhaled : If inhaled, remove to fresh air.



# Dexamethasone (0.085%) Formulation

SDS Number: Date of last issue: 30.09.2023 Version Revision Date: 1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks None known.

Protection of first-aiders No special precautions are necessary for first aid responders.

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

None known.

#### 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 prod- :

Carbon oxides Metal oxides

#### Special protective actions for fire-fighters

Special protective equipment:

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

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

Evacuate area.

### Section 6: Accidental release measures

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

Personal precautions 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.



# Dexamethasone (0.085%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.10
 06.04.2024
 2708662-00011
 Date of first issue: 13.04.2018

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.

### Methods and materials for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

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 absor-

bent.

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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety

practice, based on the results of the workplace exposure as-

sessment

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.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents



## Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

#### Section 8: Exposure controls/personal protection

#### **Control parameters**

### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Dexamethasone	50-02-2	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal	

Appropriate engineering control measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-

less quick connections).

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 : Organic vapour type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Section 9: Physical and chemical properties

Appearance : suspension



# Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : 7.0 - 7.8

No data available

Melting point/freezing point : Not applicable

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

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 : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.01 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive



# Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

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

Molecular weight : Not applicable

Particle characteristics

Particle size : Not applicable

#### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

: Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition :

products

No hazardous decomposition products are known.

### **Section 11: Toxicological information**

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

**Components:** 

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Dexamethasone:

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



# Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of : LD50 (Rat): 14 mg/kg

administration) Application Route: Subcutaneous

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

### Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

#### Dexamethasone:

Species : Rabbit

Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

### Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

### Dexamethasone:

Species : Rabbit

Result : Mild eye irritation

### Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### Benzyl alcohol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative



# Dexamethasone (0.085%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.10
 06.04.2024
 2708662-00011
 Date of first issue: 13.04.2018

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

Benzyl alcohol:

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

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

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.

#### **Components:**

#### Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

### Reproductive toxicity

Not classified based on available information.

### **Components:**

#### Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials



# Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Dexamethasone:

Effects on foetal develop-

ment

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 - 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:**

### Benzyl alcohol:

Species : Rat NOAEL : 1.072 mg/l



# Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

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.

Experience with human exposure

**Components:** 

Dexamethasone:

Ingestion : Target Organs: Immune system

Target Organs: Adrenal gland

Target Organs: Bone

Symptoms: muscle weakness



# Dexamethasone (0.085%) Formulation

SDS Number: Date of last issue: 30.09.2023 Version **Revision Date:** 1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

### **Section 12: Ecological information**

**Toxicity** 

**Components:** 

Benzyl alcohol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

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

1

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

EC50: > 1,000 mg/l

Exposure time: 3 h



## Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

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:** 

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

Dexamethasone:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 3.54 d

Method: OECD Test Guideline 314

Bioaccumulative potential

**Components:** 

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1.05

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 : 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.



## Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

#### **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
Class : 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 Not applicable UN proper shipping name Not applicable Class Subsidiary risk Not applicable Not applicable Packing group Not applicable Labels **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

#### **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.

Not applicable

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable



## Dexamethasone (0.085%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.10
 06.04.2024
 2708662-00011
 Date of first issue: 13.04.2018

#### Regulations

### 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 : 06.04.2024

**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

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 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 Recom-



# Dexamethasone (0.085%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.10 06.04.2024 2708662-00011 Date of first issue: 13.04.2018

mendations 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