

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

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**Section 1: Identification**

**Product identifier** : Dexamethasone Formulation

**Other means of identification** : DEXAFORT AQUEOUS SUSPENSION OF DEXAMETHASONE AS MIXED ESTERS (37231)

**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



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**Section 2: Hazard identification****Classification of the substance or mixture**

Skin sensitisation : Category 1

Reproductive toxicity : Category 1B

**GHS Label elements, including precautionary statements**

Hazard pictograms	:	 
Signal word	:	Danger
Hazard statements	:	H317 May cause an allergic skin reaction. H360D May damage the unborn child.
Precautionary statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P261 Avoid breathing mist or vapours.

## Dexamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
5.0	17.06.2025	1842864-00017	14.04.2025
			Date of first issue: 20.07.2017

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.

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

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**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	>= 0.3 -< 1

**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 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	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting.

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

Get medical attention.  
Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**

Risks : May cause an allergic skin reaction.  
May damage the unborn child.

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.

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**Section 5: Fire-fighting measures****Extinguishing media**

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

Unsuitable extinguishing media : 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 products : Carbon oxides  
Metal oxides

**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 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.

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**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 protective equipment recommendations (see section 8).

**Environmental precautions**

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue:
5.0	17.06.2025	1842864-00017	14.04.2025
			Date of first issue: 20.07.2017

---

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

**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 absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**Section 7: Handling and storage****Precautions for safe handling**

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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

Advice on safe handling : Do not get on skin or clothing.  
Avoid breathing mist or vapours.  
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.  
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.  
Contaminated work clothing should not be allowed out of the workplace.  
Wash contaminated clothing before re-use.

**Conditions for safe storage, including any incompatibilities**

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.

## Dexamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
5.0	17.06.2025	1842864-00017	14.04.2025
			Date of first issue: 20.07.2017

Materials to avoid : Store in accordance with the particular national regulations.  
: 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
dexamethasone	50-02-2	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**Appropriate engineering control measures** : Minimize workplace exposure concentrations.  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

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

Eye/face protection : Wear the following personal protective equipment:  
Safety glasses

Skin protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

## Section 9: Physical and chemical properties

Appearance : suspension

Colour : white to off-white

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

Odour Threshold	:	No data available
pH	:	7.0 - 7.8
Melting point/freezing point	:	No data available
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
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

**Section 10: Stability and reactivity**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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 exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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**Components:****Benzyl alcohol:**

Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation 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.

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

**Components:****Benzyl alcohol:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

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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**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Benzyl alcohol:**

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
Result	: positive

Assessment	: Probability or evidence of low to moderate skin sensitisation rate in humans
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**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Benzyl alcohol:**



**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

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**

May damage the unborn child.

**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
Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

**dexamethasone:**

Effects on foetal 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: $\geq 0.062$ mg/kg body weight
	:	Result: Specific developmental abnormalities
	:	Species: Rat
	:	Application Route: Subcutaneous
	:	Developmental Toxicity: LOAEL: $\geq 0.02$ mg/kg body weight
	:	Result: Skeletal and visceral variations, Fetal growth retardation
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:**

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
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

**dexamethasone:**

## Dexamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

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	: Dog
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
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## Dexamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

## 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 (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

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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

## Dexamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

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

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**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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

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**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 aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

**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

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**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 subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

**Dexamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue:
5.0	17.06.2025	1842864-00017	14.04.2025
			Date of first issue: 20.07.2017

**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 : 17.06.2025

**Further information**

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

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

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 Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	1842864-00017	Date of first issue: 20.07.2017

---

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.

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