Dexamethasone (0.085%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone (0.085%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : suspension
Colour : No data available
Odour : No data available

Not a hazardous substance or mixture.

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

Not classified based on available information.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification
None known.

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

4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
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 : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : None known.

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

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides

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 firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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. 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	:	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.

7. HANDLING AND STORAGE

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 assessment Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	:	Oxidizing agents

Storage

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
Packaging material	:	Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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 cm²	Internal

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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 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 : Organic vapour type

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 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
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^3
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle size	:	Not applicable

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.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 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

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:

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

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

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: >= 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:

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:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

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:

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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	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
Proper shipping name	:	Not applicable
Class	:	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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	2023/09/30

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/
Date format	:	yyyy/mm/dd

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 Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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