

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025
Date of first issue: 10.03.2020

SECTION 1. IDENTIFICATION

Product identifier : Dexamethasone (0.28%) Formulation

Other means of identification : Dexadreson (A001421)
DEXADRESON INJECTION (52298)

Manufacturer or supplier's details

Company : MSD

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

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Skin sensitization : Category 1

Long-term (chronic) aquatic hazard : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements :

Prevention:
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 5492910-00012	Date of last issue: 19.02.2025 Date of first issue: 10.03.2020
----------------	------------------------------	------------------------------	---

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6	Acute Tox. (Oral), 4 Eye Irrit., 2A Skin Sens., 1B	>= 1 -< 5
dexamethasone	50-02-2	Repr., 1B STOT RE, (Oral)(Adrenal gland, Immune system, thymus gland) , 2 Aquatic Chronic, 1	>= 0,25 -< 0,3

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : 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.
Rinse mouth thoroughly with water.
May cause an allergic skin reaction.

Most important symptoms and effects, both acute and delayed

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).

Dexamethasone (0.28%) Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 5492910-00012	Date of last issue: 19.02.2025 Date of first issue: 10.03.2020
----------------	------------------------------	------------------------------	---

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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 diking or other appropriate containment to keep material from spreading. If diked 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.

Dexamethasone (0.28%) FormulationVersion
3.0Revision Date:
14.04.2025SDS Number:
5492910-00012Date of last issue: 19.02.2025
Date of first issue: 10.03.2020

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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 vapors.
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.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
dexamethasone	50-02-2	TWA	10 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 µg/100 cm ²	Internal

Engineering measures : Use appropriate engineering controls and manufacturing

Dexamethasone (0.28%) Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 5492910-00012	Date of last issue: 19.02.2025 Date of first issue: 10.03.2020
----------------	------------------------------	------------------------------	---

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 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	: Combined particulates and organic vapor type
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: liquid
Color	: clear
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025
Date of first issue: 10.03.2020

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
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: 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	: Not applicable

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

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025 Date of first issue: 10.03.2020

Information on likely routes of exposure : 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

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.

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

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025 Date of first issue: 10.03.2020

|||Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

dexamethasone:

|||Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Benzyl alcohol:

|||Test Type : Human repeat insult patch test (HRIPT)
Routes of exposure : Skin contact
Species : Humans
Result : positive

|||Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

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 test
Test system: mouse lymphoma cells
Result: negative

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

Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025
Date of first issue: 10.03.2020

II**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 fetal development	:	Test Type: Embryo-fetal development Species: Mouse Application Route: Ingestion Result: negative

dexamethasone:

Effects on fetal development	:	Test Type: Development Species: Mouse Application Route: Subcutaneous Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: Specific developmental abnormalities., Cleft palate Species: Rabbit Application Route: Intramuscular Developmental Toxicity: NOAEL: 0,025 mg/kg body weight Result: Specific developmental abnormalities.
	:	Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: >= 0,062 mg/kg body weight Result: Specific developmental abnormalities.
	:	Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: >= 0,02 mg/kg body weight Result: Skeletal and visceral variations ., Fetal growth retardation
Reproductive toxicity - As-	:	May damage the unborn child.

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025
3.0 14.04.2025 5492910-00012 Date of first issue: 10.03.2020

Assessment

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

dexamethasone:

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

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025 Date of first issue: 10.03.2020

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

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

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 5492910-00012	Date of last issue: 19.02.2025 Date of first issue: 10.03.2020
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
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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

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 5492910-00012 Date of last issue: 19.02.2025
Date of first issue: 10.03.2020

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

Dexamethasone (0.28%) Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 5492910-00012	Date of last issue: 19.02.2025 Date of first issue: 10.03.2020
----------------	------------------------------	------------------------------	---

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
Date format : dd.mm.yyyy

Further information

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

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

Full text of other abbreviations

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

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

SAFETY DATA SHEET



Dexamethasone (0.28%) Formulation

Version
3.0

Revision Date:
14.04.2025

SDS Number:
5492910-00012

Date of last issue: 19.02.2025
Date of first issue: 10.03.2020

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