

# SAFETY DATA SHEET



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 6.0      Revision Date: 14.04.2025      SDS Number: 5491647-00015      Date of last issue: 25.02.2025  
Date of first issue: 10.03.2020

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### SECTION 1. IDENTIFICATION

Product identifier : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

#### 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 medicine

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Eye irritation : Category 2A

Respiratory sensitization : Category 1

Skin sensitization : Category 1

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (ear, Kidney, inner ear)

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

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### Precautionary Statements

#### : Prevention:

P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/ eye protection/ face protection.

#### : Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### Additional Labeling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 33,36 %

### 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)
Dihydrostreptomycin sulphate	5490-27-7	STOT RE, (Oral)(ear, Kidney, inner ear) , 1	>= 50 -< 70
2-(4-Aminobenzo- yloxy)ethyldiethylammonium (6R)-6-(2- phenylacetamido)penicillanate monohydrate	6130-64-9	Resp. Sens., 1 Skin Sens., 1	>= 30 -< 50
Procaine hydrochloride	51-05-8	Acute Tox. (Oral), 3	>= 1 -< 5
Chlorphenamine hydrogen maleate	113-92-8	Eye Dam., 1 STOT SE, 3 STOT RE, (Oral)(Cardio-vascular system) , 2	>= 1 -< 3

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dexamethasone	50-02-2	Repr., 1B STOT RE, (Oral)(Adrenal gland, Immune system, thymus gland) , 2 Aquatic Chronic, 1	>= 0,025 -< 0,1
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### 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.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.

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 : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).  
May cause an allergic skin reaction.  
Causes serious eye irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Causes damage to organs through prolonged or repeated exposure if swallowed.

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).

Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

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

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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 Nitrogen oxides (NOx) Sulfur oxides Chlorine compounds 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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

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Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers. Do not eat, drink or smoke when using this product. 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
Dihydrostreptomycin sulphate	5490-27-7	TWA	4 mg/m3 (OEB 1)	
	Further information: OTO			
Chlorphenamine hydrogen maleate	113-92-8	TWA	10 µg/m3 (OEB 3)	Internal
	Further information: Skin			

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		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
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

**Engineering 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 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	
Hand protection	: Particulates type
Material	: Chemical-resistant gloves
Remarks	
Eye protection	: Consider double gloving. : 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	: suspension
Color	: white
Odor	: No data available
Odor Threshold	: No data available
pH	: 5,0 - 6,0 No data available

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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)	: Not applicable
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	: 1,17 - 1,21 g/cm <sup>3</sup> 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

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## SECTION 10. STABILITY AND REACTIVITY

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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.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

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:****Dihydrostreptomycin sulphate:**

Acute oral toxicity : LD50 (Rat): 9.000 - 25.000 mg/kg  
LD50 Oral (Mouse): 30.000 mg/kg

**2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

Acute oral toxicity : LD50 (Mouse): > 2.000 mg/kg

**Procaine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 200 mg/kg

**Chlorphenamine hydrogen maleate:**

Acute inhalation toxicity : LC50 (Rat): 0,61 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 89 mg/kg

**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

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**Skin corrosion/irritation**

Not classified based on available information.

**Components:****2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

||Result : No skin irritation

**Chlorphenamine hydrogen maleate:**||Species : Rabbit  
||Result : No skin irritation**dexamethasone:**||Species : Rabbit  
||Result : Mild skin irritation**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

||Result : No eye irritation

**Chlorphenamine hydrogen maleate:**||Species : Rabbit  
||Result : Severe irritation**dexamethasone:**||Species : Rabbit  
||Result : Mild eye irritation**Respiratory or skin sensitization****Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:****2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**||Test Type : Maximization Test  
||Routes of exposure : Skin contact  
||Species : Guinea pig

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Method	:	OECD Test Guideline 406
Result	:	positive
Remarks	:	Based on data from similar materials
Assessment	:	Probability or evidence of skin sensitization in humans
Assessment	:	Probability of respiratory sensitization in humans based on animal testing

## **Chlorphenamine hydrogen maleate:**

Routes of exposure : Dermal  
Remarks : No data available

## Germ cell mutagenicity

Not classified based on available information.

## Components:

### **Dihydrostreptomycin sulphate:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Test system: Human lymphocytes  
Result: negative

## Procaine hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

## **Chlorphenamine hydrogen maleate:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Mouse Lymphoma Result: negative
	Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: positive
	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: rat hepatocytes Result: negative
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen

## **dexamethasone-**

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

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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

**Carcinogenicity**

Not classified based on available information.

**Components:****Dihydrostreptomycin sulphate:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 5 mg/kg body weight  
Result : negative

**Chlorphenamine hydrogen maleate:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 30 - 60 mg/kg body weight  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 20 - 50 mg/kg body weight  
Result : negative

**Reproductive toxicity**

Not classified based on available information.

**Components:****Dihydrostreptomycin sulphate:**

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-fetal development  
Species: Guinea pig  
Application Route: Intramuscular  
General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body weight  
Developmental Toxicity: NOAEL: 10 mg/kg body weight

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Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.

**Chlorphenamine hydrogen maleate:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 20 mg/kg body weight  
Result: No effects on fertility., No effects on fetal development.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: Reduced embryonic survival, No malformations were observed.  
Remarks: The significance of these findings for humans is not certain.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 15 mg/kg body weight  
Result: No significant adverse effects were reported

**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 - Assessment : May damage the unborn child.

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Not classified based on available information.

**Components:****Chlorphenamine hydrogen maleate:**

Assessment	: May cause drowsiness or dizziness.
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**STOT-repeated exposure**

Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

**Components:****Dihydrostreptomycin sulphate:**

Assessment	: Causes damage to organs through prolonged or repeated exposure.
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**Chlorphenamine hydrogen maleate:**

Target Organs	: Cardio-vascular system
Assessment	: May cause damage to organs through prolonged or repeated exposure.

**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:****Dihydrostreptomycin sulphate:**

Species	: Guinea pig
LOAEL	: 40 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: ear
Symptoms	: hearing loss

Species	: Cat
LOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 60 d
Target Organs	: ear
Symptoms	: ataxia, hearing loss, Reduced body weight

Species	: Cat
LOAEL	: 300 mg/kg
Application Route	: Oral
Exposure time	: 21 d

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Target Organs : ear  
Symptoms : ataxia, hearing loss, Reduced body weight

**Chlorphenamine hydrogen maleate:**

Species : Rat  
NOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 6 Weeks  
Remarks : No significant adverse effects were reported

Species : Monkey  
LOAEL : 15 mg/kg  
Application Route : Oral  
Exposure time : 105 Weeks  
Target Organs : Heart

**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

Species : Dog  
LOAEL : 8 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Immune system  
Remarks : Significant toxicity observed in testing

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Not classified based on available information.

**Experience with human exposure****Components:****Dihydrostreptomycin sulphate:**

General Information : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension

**Chlorphenamine hydrogen maleate:**

Inhalation : Symptoms: central nervous system effects  
Remarks: May cause respiratory tract irritation.

Skin contact : Remarks: May irritate skin.

Eye contact : Symptoms: Eye irritation  
Remarks: May cause irreversible eye damage.

Ingestion : Symptoms: central nervous system effects  
Remarks: Based on Human Evidence

**dexamethasone:**

Ingestion : Target Organs: Immune system  
Target Organs: Adrenal gland  
Target Organs: Bone  
Symptoms: muscle weakness

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:****Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

**Procaine hydrochloride:****Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

**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 : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,2

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plants	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:

##### **dexamethasone:**

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 50 % Exposure time: 3,54 d Method: OECD Test Guideline 314
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### Bioaccumulative potential

#### Components:

##### **Procaine hydrochloride:**

Partition coefficient: n-octanol/water	: log Pow: 1,389
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##### **dexamethasone:**

Partition coefficient: n-octanol/water	: log Pow: 1,83
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### 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.

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### 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

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### 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

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### SECTION 16. OTHER INFORMATION

# SAFETY DATA SHEET



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 6.0	Revision Date: 14.04.2025	SDS Number: 5491647-00015	Date of last issue: 25.02.2025 Date of first issue: 10.03.2020
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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 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

# SAFETY DATA SHEET



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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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