

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

### SECTION 1. IDENTIFICATION

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary medicine  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4  
Eye irritation : Category 2A  
Respiratory sensitization : Category 1  
Skin sensitization : Category 1  
Reproductive toxicity : Category 2  
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Cardio-vascular system)

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

### Precautionary Statements

:

#### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
P285 In case of inadequate ventilation wear respiratory protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P304 + P341 IF INHALED: If breathing is difficult, 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.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.  
P363 Wash contaminated clothing before reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Dihydrostreptomycin sulphate	5490-27-7	>= 50 - < 70
2-(4-Aminobenzyloxy)ethyl-diethylammonium (6R)-6-	6130-64-9	>= 30 - < 50

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

(2-phenylacetamido)penicillanate monohydrate		
Procaine hydrochloride	51-05-8	$\geq 1 - < 5$
Chlorphenamine hydrogen maleate	113-92-8	$\geq 1 - < 5$
Dexamethasone	50-02-2	$< 0.1$

Actual concentration is withheld as a trade secret

### 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.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.  
May cause an allergic skin reaction.  
Causes serious eye irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure if swallowed.  
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

---

Unsuitable extinguishing media	:	Carbon dioxide (CO <sub>2</sub> ) Dry chemical None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) 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

Technical measures	:	See Engineering measures under EXPOSURE
--------------------	---	---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
Advice on safe handling : Use only with adequate ventilation.  
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.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
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  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dihydrostreptomycin sulphate	5490-27-7	TWA	OEB 2 ( $\geq 100 < 1000 \mu\text{g}/\text{m}^3$ )	Internal
		TWA	$0.4 \text{ mg}/\text{m}^3$	Customer derived OEL
Chlorphenamine hydrogen maleate	113-92-8	TWA	$10 \mu\text{g}/\text{m}^3$ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	$100 \mu\text{g}/100 \text{ cm}^2$	Internal
Dexamethasone	50-02-2	TWA	$10 \mu\text{g}/\text{m}^3$ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	$100 \mu\text{g}/100 \text{ cm}^2$	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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
- 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.
- 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

---

Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	5.0 - 6.0 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
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

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

Molecular weight : No data available

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

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 709.59 mg/kg  
Method: Calculation method

#### Components:

##### Dihydrostreptomycin sulphate:

Acute oral toxicity : LD50 (Rat): 430 mg/kg  
Remarks: Based on data from similar materials

##### 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



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

---

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

### **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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

---

### 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:

##### Dihydrostreptomycin sulphate:

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : positive  
Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitization in humans

##### 2-(4-Aminobenzoyloxy)ethyl-diethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
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:

##### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

---

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

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:**

#### **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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

---

on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Dihydrostreptomycin sulphate:

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

#### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

---

Result: Specific developmental abnormalities.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL:  $\geq 0.02$  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.

### Components:

#### Chlorphenamine hydrogen maleate:

Assessment : May cause drowsiness or dizziness.

### STOT-repeated exposure

May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

### Components:

#### 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:

#### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

---

### 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:

#### Dihydrostreptomycin sulphate:

General Information : Target Organs: ear  
Symptoms: hearing loss

#### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

Ingestion : Remarks: May cause irreversible eye damage.  
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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Dihydrostreptomycin sulphate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50: > 0.01 - 0.1 mg/l  
Remarks: Based on data from similar materials

#### 2-(4-Aminobenzoyloxy)ethyl-diethylammonium (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 plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l  
Exposure time: 72 h

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

---

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

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

### Bioaccumulative potential

#### Components:

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

Bioaccumulation : Species: Fish  
Bioconcentration factor (BCF): 3.16

Partition coefficient: n-octanol/water : log Pow: -7.51

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

Partition coefficient: n-octanol/water : log Pow: 1.389

##### **Dexamethasone:**

Partition coefficient: n-octanol/water : log Pow: 1.83

### Mobility in soil

No data available



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.  
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

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Dihydrostreptomycin sulphate)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Dihydrostreptomycin sulphate)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

#### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Dihydrostreptomycin sulphate)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

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

Not applicable for product as supplied.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

### Domestic regulation

#### 49 CFR

UN/ID/NA number	: UN 3082
Proper shipping name	: Environmentally hazardous substance, liquid, n.o.s. (Dihydrostreptomycin sulphate)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(Dihydrostreptomycin sulphate)
Remarks	: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

<b>SARA 311/312 Hazards</b>	: Acute toxicity (any route of exposure) Respiratory or skin sensitization Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Serious eye damage or eye irritation
-----------------------------	--

<b>SARA 313</b>	: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
-----------------	---

### US State Regulations

#### Pennsylvania Right To Know

Dihydrostreptomycin sulphate	5490-27-7
2-(4-Aminobenzoyloxy)ethyl-diethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate	6130-64-9
Water	7732-18-5

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

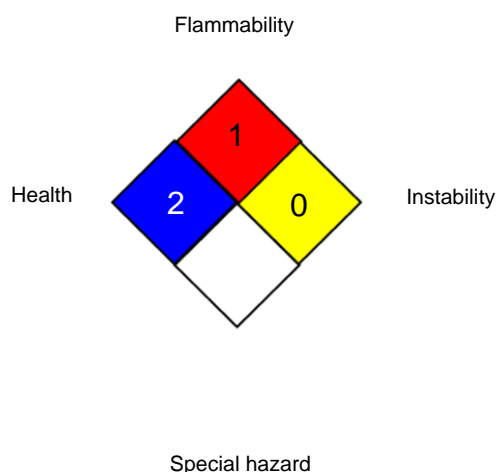
Version 2.6      Revision Date: 09/30/2023      SDS Number: 5491621-00011      Date of last issue: 04/04/2023  
Date of first issue: 03/10/2020

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

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.6	09/30/2023	5491621-00011	Date of first issue: 03/10/2020

---

erwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Revision Date : 09/30/2023

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.

US / Z8