

## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 2.2      Revision Date: 10/01/2022      SDS Number: 5491648-00008      Date of last issue: 04/09/2022  
Date of first issue: 03/10/2020

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### SECTION 1. IDENTIFICATION

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation  
Other means of identification : No data available

#### 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



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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

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)

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through prolonged or repeated exposure if swallowed.

### 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 should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing, eye protection and face protection.

P284 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 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.

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.

P362 + P364 Take off contaminated clothing and wash it 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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Dihydrostreptomycin sulphate	D-Streptomine, O-2-deoxy-2-(methylamino)-	5490-27-7	>= 30 - < 60 *

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	.alpha.-L-glucopyranosyl-(1->2)-O-5-deoxy-3-C-(hydroxymethyl)-.alpha.-L-lyxofuranosyl-(1->4		
2-(4-Aminobenzyloxy)ethyl-diethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate	No data available	6130-64-9	$\geq 30 - < 60$ *
Procaine hydrochloride	Benzoic acid, 4-amino-, 2-(diethylamino)ethyl ester, hydrochloride (1:1)	51-05-8	$\geq 1 - < 5$ *
Chlorphenamine hydrogen maleate	No data available	113-92-8	$\geq 1 - < 5$ *
Dexamethasone	No data available	50-02-2	$\geq 0 - < 0.1$ *

\* Actual concentration or concentration range 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.

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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.

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### SECTION 5. FIRE-FIGHTING MEASURES

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

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### 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.

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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 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.

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 (>= 100 <	Internal

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			1000 µg/m <sup>3</sup> )	
		TWA	0.4 mg/m <sup>3</sup>	Customer derived OEL
Chlorphenamine hydrogen maleate	113-92-8	TWA	10 µg/m <sup>3</sup>	Internal
	Further information: Skin			
		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** : Particulates 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.

**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

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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
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

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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 size : Not applicable

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### 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.

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### 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: 662.58 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 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

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**Procaine hydrochloride:**

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

**Chlorphenamine hydrogen maleate:**

Acute oral toxicity : LD50 (Rat): 118 - 306 mg/kg

LD50 (Mouse): 130 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.61 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): 365 mg/kg

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.

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### 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:

#### **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)ethyldiethylammonium (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

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### 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

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

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

### 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

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Application Route: Intramuscular  
Developmental Toxicity: LOAEL:  $\geq 0.062$  mg/kg body weight  
Result: Specific developmental abnormalities.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL:  $\geq 0.02$  mg/kg body weight  
Result: Skeletal and visceral variations ., 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

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### 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

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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

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

Toxicity to algae/aquatic : EC50: > 0.01 - 0.1 mg/l  
plants : 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 : EC50 (Daphnia magna (Water flea)): > 56 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2  
plants : mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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- 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

**Other adverse effects**

No data available



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### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : 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

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

##### 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.

#### Domestic regulation

##### TDG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

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		(Dihydrostreptomycin sulphate)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Dihydrostreptomycin sulphate)

### 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

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

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

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AIC - 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 Tempera-

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ture; 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

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 : 10/01/2022  
Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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