

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary medicine

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

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. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. <b>Response:</b> P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor. P391 Collect spillage.

Hazardous components which must be listed on the label:

Dihydrostreptomycin sulphate  
2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate  
Procaine hydrochloride

### Additional Labelling

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

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Dihydrostreptomycin sulphate	5490-27-7 226-823-7	Acute Tox. 4; H302 Skin Sens. 1; H317 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10  Acute toxicity esti- mate  Acute oral toxicity: 430 mg/kg	>= 50 - < 70
2-(4-Aminobenzo- yloxy)ethyldiethylammonium (6R)-6- (2-phenylacetamido)penicillanate monohydrate	6130-64-9	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 30 - < 50
Procaine hydrochloride	51-05-8 200-077-2	Acute Tox. 3; H301  Acute toxicity esti- mate  Acute oral toxicity: 200 mg/kg	>= 1 - < 10
Chlorphenamine hydrogen maleate	113-92-8 204-037-5	Eye Dam. 1; H318 STOT SE 3; H336 STOT RE 2; H373 (Cardio-vascular system)	>= 1 - < 3
Dexamethasone	50-02-2 200-003-9	Repr. 1B; H360D STOT RE 2; H373 (Adrenal gland, Immune system, thymus gland) Aquatic Chronic 1;	>= 0,025 - < 0,1

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

		H410	
		M-Factor (Chronic aquatic toxicity): 1	

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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>)  
Sulphur oxides  
Chlorine compounds  
Metal oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

---

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

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 vapours.  
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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Dihydrostreptomycin sulphate	5490-27-7	TWA	OEB 2 ( $\geq 100 < 1000$ $\mu\text{g}/\text{m}^3$ )	Internal
		TWA	0,4 mg/m <sup>3</sup>	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 $\mu\text{g}/100$ cm <sup>2</sup>	Internal
Dexamethasone	50-02-2	TWA	10 $\mu\text{g}/\text{m}^3$ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 $\mu\text{g}/100$ cm <sup>2</sup>	Internal

### 8.2 Exposure controls

#### 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 Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

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

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

---

Lower explosion limit / Lower  
flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 5,0 - 6,0  
No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : 1,17 - 1,21 g/cm<sup>3</sup>  
No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

---

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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:

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

---

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

### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

### Dexamethasone:

Species : Rabbit  
Result : Mild eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

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

### Components:

#### Dihydrostreptomycin sulphate:

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

Assessment : Probability or evidence of skin sensitisation in humans

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

Test Type : Maximisation Test  
Exposure routes : 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 sensitisation in humans

Assessment : Probability of respiratory sensitisation in humans based on animal testing

#### Chlorphenamine hydrogen maleate:

Exposure routes : 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

---

### 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 assay  
Test system: mouse lymphoma cells  
Result: negative

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

---

### 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 foetal development

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

#### Dexamethasone:

Effects on foetal development : Test Type: Development  
Species: Mouse  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 6 mg/kg body weight  
Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: NOAEL: 0,025 mg/kg body weight  
Result: Specific developmental abnormalities

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL:  $\geq 0,062$  mg/kg body weight  
Result: Specific developmental abnormalities

Species: Rat

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

---

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

Not classified based on available information.

#### Components:

##### **Chlorphenamine hydrogen maleate:**

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

##### **Dexamethasone:**

Exposure routes : Oral  
Target Organs : Adrenal gland, Immune system, thymus gland  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

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.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 5500083-00012      Date of last issue: 04.04.2023  
Date of first issue: 10.03.2020

---

### 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  
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

---

## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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

M-Factor (Acute aquatic toxicity) : 10

M-Factor (Chronic aquatic toxicity) : 10

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

#### **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

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  
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 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

Toxicity to fish (Chronic toxicity) : NOEC: 0,033 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity) : 1

## 12.2 Persistence and degradability

### Components:

#### Dexamethasone:

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 3,54 d

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

Method: OECD Test Guideline 314

### 12.3 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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in  
discussion with the waste disposal authorities.  
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

#### 14.1 UN number or ID number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

#### 14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
IATA	:	Environmentally hazardous substance, liquid, n.o.s. (Dihydrostreptomycin sulphate)

#### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

#### 14.4 Packing group

ADN

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

### ADR

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

### RID

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

Other information	:	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 H-Statements

H301	:	Toxic if swallowed.
H302	:	Harmful if swallowed.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H336	:	May cause drowsiness or dizziness.
H360D	:	May damage the unborn child.
H361d	:	Suspected of damaging the unborn child.
H373	:	May cause damage to organs through prolonged or repeated exposure if swallowed.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Repr.	:	Reproductive toxicity
Resp. Sens.	:	Respiratory sensitisation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

### Further information

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

### Classification of the mixture:

Acute Tox. 4	H302
Eye Irrit. 2	H319
Resp. Sens. 1	H334
Skin Sens. 1	H317
Repr. 2	H361d
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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 mate-



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	5500083-00012	Date of first issue: 10.03.2020

---

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.

NO / EN