

# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formu-

lation

Manufacturer or supplier's details

Company name of supplier : MSD

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@msd.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** 

Acute toxicity (Oral) : Category 4

Serious eye damage/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 diffi-

culties 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.



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

**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 should not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P284 Wear respiratory protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

CENTER or doctor/ physician 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 advice/attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P362 + P364 Take off contaminated clothing and wash it before reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ 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-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate	6130-64-9	>= 30 -< 50



## Dexamethasone / Chlorphenamine Hydrogen **Maleate Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 5491619-00011 Date of first issue: 10.03.2020 3.1

Procaine hydrochloride	51-05-8	>= 1 -< 5
Chlorphenamine hydrogen maleate	113-92-8	>= 1 -< 3
Dexamethasone	50-02-2	< 0.1

#### **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, DO NOT induce vomiting. If swallowed

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 Harmful if swallowed.

May cause an allergic skin reaction.

delayed

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficul-

ties 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, reac-

tive airways dysfunction syndrome).

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.



## **Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 5491619-00011 Date of first issue: 10.03.2020 3.1

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides Nitrogen oxides (NOx)

Sulfur oxides

Chlorine compounds

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec: :

tive 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

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Do not get on skin or clothing. Advice on safe handling

Do not breathe mist or vapors.

Use only with adequate ventilation.

Do not swallow.



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5491619-00011 Date of first issue: 10.03.2020

Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

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

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

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 < 1000 μg/m3)	Internal	
		TWA	0.4 mg/m <sup>3</sup>	Customer derived OEL	
Chlorphenamine hydrogen maleate	113-92-8	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	100 μg/100 cm2	Internal	
Dexamethasone	50-02-2	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal	



## Dexamethasone / Chlorphenamine Hydrogen **Maleate Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 5491619-00011 Date of first issue: 10.03.2020 3.1

**Engineering measures** Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

Material Chemical-resistant gloves

Remarks Consider double gloving.

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection Work uniform or laboratory coat.

> Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES** 

Appearance suspension

Color white

Odor No data available

Odor Threshold No data available

5.0 - 6.0pΗ

No data available

Melting point/freezing point No data available

Initial boiling point and boiling : No data available

range



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.17 - 1.21 g/cm<sup>3</sup>

No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents



## **Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 5491619-00011 Date of first issue: 10.03.2020 3.1

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

Test atmosphere: dust/mist

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

administration)

Dexamethasone:

LD50 (Rat): > 2,000 mg/kg Acute oral toxicity

LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of :

LD50 (Rat): 14 mg/kg

administration)

Application Route: Subcutaneous

#### Skin corrosion/irritation

Not classified based on available information.



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

## **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:** 

 $\hbox{2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)} penicillanate$ 

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



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

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

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 syn-

thesis 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



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5491619-00011 Date of first issue: 10.03.2020

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

#### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Dihydrostreptomycin sulphate:

Reproductive toxicity - As-

sessment

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.



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5491619-00011 Date of first issue: 10.03.2020

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 15 mg/kg body weight Result: No significant adverse effects were reported

Dexamethasone:

Effects on fetal development : Test Type: Development

Species: Mouse

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: Specific developmental abnormalities., Cleft palate

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: NOAEL: 0.025 mg/kg body weight

Result: Specific developmental abnormalities.

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: >= 0.062 mg/kg body weight

Result: Specific developmental abnormalities.

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: >= 0.02 mg/kg body weight Result: Skeletal and visceral variations ., Retardations.

Reproductive toxicity - As-

sessment

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



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

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 : 105 Week

#### 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



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

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

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** 

**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

: EC50: > 0.01 - 0.1 mg/l

plants

Remarks: Based on data from similar materials



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

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

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Procaine hydrochloride:

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Dexamethasone:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 56 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

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



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5491619-00011 Date of first issue: 10.03.2020

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

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

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)



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5491619-00011
 Date of first issue: 10.03.2020

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

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**

NOM-002-SCT

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Dihydrostreptomycin sulphate)

Class : 9
Packing group : III
Labels : 9

#### 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**

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

Not applicable

producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined



## Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5491619-00011 Date of first issue: 10.03.2020

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 30.09.2023 Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil: ASTM - American Society for the Testing of Materials: bw - Body weight: CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 Agen-

cy, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8