according to the Hazardous Products Regulations



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 02/25/2025 4.0 04/14/2025 5491648-00015 Date of first issue: 03/10/2020

## **SECTION 1. IDENTIFICATION**

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formu-

lation

Other means of identification : No data available

## Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary medicine Restrictions on use : Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the Hazardous Products Regulations

Eye irritation : Category 2A

Respiratory sensitization : Category 1

Skin sensitization : Category 1

Specific target organ toxicity - repeated exposure (Oral)

Category 1 (ear, Kidney, inner ear)

Specific target organ toxicity - repeated exposure (Oral)

Category 2 (Cardio-vascular system)

## **GHS** label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.
H373 May cause damage to organs (Cardio-vascular system)

through prolonged or repeated exposure if swallowed.

according to the Hazardous Products Regulations



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**Precautionary Statements** 

### Prevention:

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, eye protection and face protection

P284 Wear respiratory protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P337 + P313 If eye irritation persists: Get medical attention. P342 + P311 If experiencing respiratory symptoms: Call a doc-

P362 + P364 Take off contaminated clothing and wash it before

reuse.

## 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	No data availa- ble	5490-27-7	>= 30 - < 60 *
2-(4- Aminobenzo- yloxy)ethyldiethylammo nium (6R)-6-(2- phenylacetam- ido)penicillanate mon- ohydrate		6130-64-9	>= 30 - < 60 *
Procaine hydrochloride	Benzoic acid, 4-amino-, 2-	51-05-8	>= 1 - < 5 *

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	(diethyla- mino)ethyl es- ter, hydrochlo- ride (1:1)		
Chlorphenamine hydrogen maleate	No data availa- ble	113-92-8	>= 1 - < 5 *
dexamethasone	No data availa- ble	50-02-2	>= 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, DO NOT induce vomiting.

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delaved

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g., employeems, bronchitis

other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

May cause an allergic skin reaction.

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

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

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

Notes to physician : Treat symptomatically and supportively.

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

Suitable extinguishing media : Water spray

Alcohol-resistant foam

according to the Hazardous Products Regulations



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Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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, protective equipment and emer-

gency 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

according to the Hazardous Products Regulations



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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.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis		
		exposure)	concentration			
Dihydrostreptomycin sulphate	5490-27-7	TWA	4 mg/m3 (OEB 1)			
	Further information: OTO					
Chlorphenamine hydrogen	113-92-8	TWA	10 μg/m3 (OEB 3)	Internal		
maleate						
	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		

according to the Hazardous Products Regulations



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**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.

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

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

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

use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES** 

Appearance : suspension

Color : white

according to the Hazardous Products Regulations



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Odor : No data available

Odor Threshold : No data available

pH : 5.0 - 6.0

No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

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

No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

according to the Hazardous Products Regulations



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Molecular weight : No data available

Particle characteristics

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- : Can react with strong oxidizing agents.

tions

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

Hazardous decomposition : No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

## **Components:**

## Dihydrostreptomycin sulphate:

Acute oral toxicity : LD50 (Rat): 9,000 - 25,000 mg/kg

LD50 Oral (Mouse): 30,000 mg/kg

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

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

Procaine hydrochloride:

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

Chlorphenamine hydrogen maleate:

Acute inhalation toxicity : LC50 (Rat): 0.61 mg/l

Exposure time: 4 h

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Test atmosphere: dust/mist

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

administration)

dexamethasone:

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

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.

## **Components:**

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

Result No skin irritation

## Chlorphenamine hydrogen maleate:

**Species** Rabbit

Result No skin irritation

dexamethasone:

Species Rabbit

Result Mild skin irritation

## Serious eye damage/eye irritation

Causes serious eye irritation.

## **Components:**

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

Result No eye irritation

## Chlorphenamine hydrogen maleate:

Species Rabbit

Result Severe irritation

dexamethasone:

Species Rabbit

Result Mild eye irritation

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### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

## Respiratory sensitization

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

## Components:

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

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

Method : OECD Test Guideline 406

Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitization in humans

Assessment : Probability of respiratory sensitization in humans based on

animal testing

## Chlorphenamine hydrogen maleate:

Routes of exposure : Dermal

Remarks : No data available

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

## Dihydrostreptomycin sulphate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Result: negative

## **Procaine hydrochloride:**

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

Result: negative

Remarks: Based on data from similar materials

## Chlorphenamine hydrogen maleate:

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

Result: negative

Test Type: Mouse Lymphoma

Result: negative

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> 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

Test Type: in vitro test

Test system: mouse lymphoma cells

Result: negative

Genotoxicity in vivo Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Dihydrostreptomycin sulphate:

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

: 5 mg/kg body weight

Result : negative

Chlorphenamine hydrogen maleate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 30 - 60 r
Result : negative

: 30 - 60 mg/kg body weight

Result : negative

: Mouse Species Species : Mous
Application Route : Oral
Exposure time : 2 Yes : 2 Years

NOAEL : 20 - 50 mg/kg body weight

Result : negative

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## Reproductive toxicity

Not classified based on available information.

#### **Components:**

## Dihydrostreptomycin sulphate:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-fetal development

Species: Guinea pig

Application Route: Intramuscular

General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body

weight

Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Maternal toxicity observed., Embryotoxic effects and

adverse effects on the offspring were detected.

#### Chlorphenamine hydrogen maleate:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Fertility: LOAEL: 20 mg/kg body weight

Result: No effects on fertility., No effects on fetal development.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse Application Route: Oral

Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Reduced embryonic survival, No malformations were

observed.

Remarks: The significance of these findings for humans is not

certain.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

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

### dexamethasone:

Effects on fetal development : Test Type: Development

Species: Mouse

Application Route: Subcutaneous

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

Species: Rabbit

Application Route: Intramuscular

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Developmental Toxicity: NOAEL: 0.025 mg/kg body weight

Result: Specific developmental abnormalities.

Species: Rabbit

Application Route: Intramuscular

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

Result: Specific developmental abnormalities.

Species: Rat

Application Route: Subcutaneous

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

retardation

Reproductive toxicity - 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

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

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

### **Components:**

# Dihydrostreptomycin sulphate:

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### 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.

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### Repeated dose toxicity

### **Components:**

### Dihydrostreptomycin sulphate:

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

: hearing loss Symptoms

Species Cat

LOAEL 100 mg/kg Application Route
Exposure time Oral 60 d Target Organs ear

Symptoms ataxia, hearing loss, Reduced body weight

Species Cat LOAEL 300 mg/kg Application Route
Exposure time Oral 21 d Target Organs ear

Symptoms ataxia, hearing loss, Reduced body weight

## Chlorphenamine hydrogen maleate:

**Species** Rat NOAEL :
Application Route :
Exposure time :
Remarks : 10 mg/kg Oral 6 Weeks

Remarks No significant adverse effects were reported

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

#### dexamethasone:

Species Rat

NOAEL 0.0015 mg/kg

Application Route Oral : 7 d Exposure time Target Organs : Liver

Remarks Significant toxicity observed in testing

Species Rat

LOAEL 0.003 mg/kg

Application Route : Oral Exposure time 90 d

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Target Organs : Blood, Adrenal gland, thymus gland Remarks : Significant toxicity observed in testing

Species : Dog

LOAEL : 0.125 mg/kg

Application Route : Oral
Exposure time : 6 Weeks
Target Organs : Adrenal gland

Remarks : Significant toxicity observed in testing

Species: RatLOAEL: 0.4 mg/kgApplication Route: OralExposure time: 3 Months

Target Organs : Immune system

Remarks : Significant toxicity observed in testing

Species: DogLOAEL: 8 mg/kgApplication Route: OralExposure 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 : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting,

Headache, hypotension

#### Chlorphenamine hydrogen maleate:

Inhalation : Symptoms: central nervous system effects

Remarks: May cause respiratory tract irritation.

Skin contact : Remarks: May irritate skin. Eye contact : Symptoms: Eye irritation

Remarks: May cause irreversible eye damage.

Ingestion : Symptoms: central nervous system effects

Remarks: Based on Human Evidence

dexamethasone:

Ingestion : Target Organs: Immune system

Target Organs: Adrenal gland

Target Organs: Bone

Symptoms: muscle weakness

according to the Hazardous Products Regulations



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#### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

## **Components:**

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

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

**Procaine hydrochloride:** 

**Ecotoxicology Assessment** 

: Toxic effects cannot be excluded Acute aquatic toxicity

Chronic aquatic toxicity Toxic effects cannot be excluded

dexamethasone:

aquatic invertebrates

Toxicity to daphnia and other : 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

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

according to the Hazardous Products Regulations



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## 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:**

**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** 

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation** 

according to the Hazardous Products Regulations



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**TDG** 

Not regulated as a dangerous good

Special precautions for user

Not applicable

#### **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

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

according to the Hazardous Products Regulations



# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 02/25/2025 4.0 04/14/2025 5491648-00015 Date of first issue: 03/10/2020

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/

Revision Date : 04/14/2025 Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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