

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5491642-00015

Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Section 1: Identification

Product identifier : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary medicine
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive
Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Serious eye damage/eye irritation : Category 2

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (ear, Kidney, inner ear)

GHS Label elements, including precautionary statements

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

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

difficulties if inhaled.

H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary statements**: Prevention:**

P260 Do not breathe mist or vapours.

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/ 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 advice/ attention.

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

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

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

: Disposal:

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

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 33.36 %

Other hazards which do not result in classification

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)ethylidethyldiammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate	6130-64-9	>= 30 -< 50

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5491642-00015 Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Procaine hydrochloride	51-05-8	>= 1 -< 10
Chlorphenamine hydrogen maleate	113-92-8	>= 1 -< 3
dexamethasone	50-02-2	>= 0.025 -< 0.1

Section 4: First-aid measures**Description of necessary first-aid measures**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : Excessive exposure may aggravate preexisting asthma and 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures**Extinguishing media**

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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_x)
Sulphur oxides
Chlorine compounds
Metal oxides

Special protective actions for fire-fighters

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**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).

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.

Methods and materials 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

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 5491642-00015	Date of last issue: 25.02.2025 Date of first issue: 10.03.2020
----------------	------------------------------	------------------------------	---

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

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 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, including any incompatibilities

Conditions for safe storage	: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types:

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version Revision Date: SDS Number: Date of last issue: 25.02.2025
5.0 14.04.2025 5491642-00015 Date of first issue: 10.03.2020

Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Dihydrostreptomycin sulphate	5490-27-7	TWA	4 mg/m3 (OEB 1)	
	Further information: OTO			
Chlorphenamine hydrogen maleate	113-92-8	TWA	10 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 µg/100 cm ²	Internal
dexamethasone	50-02-2	TWA	10 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 µg/100 cm ²	Internal

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

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.

Work uniform or laboratory coat.

Respiratory protection

- 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.
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5491642-00015 Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Filter type : Particulates type
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Section 9: Physical and chemical properties

Appearance : suspension

Colour : white

Odour : No data available

Odour 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

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.17 - 1.21 g/cm³
No data available

Solubility(ies)
Water solubility : No data available

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5491642-00015

Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition 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 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 reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
--	---	--

Acute toxicity

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
---------------------	---	----------------------------------

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

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
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/kgAcute 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.

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020**Components:****2-(4-Aminobenzyloxy)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 sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

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

Components:**2-(4-Aminobenzyloxy)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:**Dihydrostreptomycin sulphate:**

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 5.0

Revision Date: 14.04.2025

SDS Number: 5491642-00015

Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

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

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:**Dihydrostreptomycin sulphate:**

Species : Rat

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5491642-00015

Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Application Route	:	Oral
Exposure time	:	2 Years
NOAEL	:	5 mg/kg body weight
Result	:	negative

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

Not classified based on available information.

Components:

Dihydrostreptomycin sulphate:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 5 mg/kg body weight
	:	Test Type: Embryo-foetal 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 foetal development
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

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: >= 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 - 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

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

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020**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:

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:****Dihydrostreptomycin sulphate:**

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

Species	: Cat
LOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 60 d
Target Organs	: ear
Symptoms	: ataxia, hearing loss, Reduced body weight

Species	: Cat
LOAEL	: 300 mg/kg
Application Route	: Oral
Exposure time	: 21 d
Target Organs	: ear
Symptoms	: ataxia, hearing loss, Reduced body weight

Chlorphenamine hydrogen maleate:

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

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020**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
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	:	Dog
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.

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020**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

Section 12: Ecological information**Toxicity****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**

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

Dexamethasone / Chlorphenamine Hydrogen Maleate FormulationVersion
5.0Revision Date:
14.04.2025SDS Number:
5491642-00015Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

plants	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 toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
M-Factor (Chronic aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
	NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability**Components:****dexamethasone:**

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 50 % Exposure time: 3.54 d Method: OECD Test Guideline 314
------------------	--

Bioaccumulative potential**Components:****Procaine hydrochloride:**

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

dexamethasone:

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

Mobility in soil

No data available

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5491642-00015

Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

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 : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5491642-00015 Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

Special precautions for user

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 14.04.2025

Further information

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

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

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 Chemi-

SAFETY DATA SHEET



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5491642-00015

Date of last issue: 25.02.2025
Date of first issue: 10.03.2020

cal 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

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

SG / EN