according to the Globally Harmonized System



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

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 SDS Number:
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 5491617-00012
 Date of first issue: 10.03.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formula-

tion

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Acute toxicity (Oral) : Category 4

Serious eye damage/eye irri-

tation

Category 2A

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Short-term (acute) aquatic

hazard

: Category 1

Long-term (chronic) aquatic

hazard

Category 1

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GHS label elements

Hazard pictograms







Signal word : Danger

Hazard statements : H302 Harmful if swallowed.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H361d Suspected of damaging the unborn child. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

P203 Obtain, read and follow all safety instructions before use.

P233 Keep container tightly closed.

P260 Do not breathe mist or vapours.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or with adequate ventilation.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

P284 Wear respiratory protection.

Response:

P301 + P317 + P330 IF SWALLOWED: Get medical help. 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.

P318 IF exposed or concerned, get medical advice.

P333 + P317 If skin irritation or rash occurs: Get medical help.

P337 + P317 If eye irritation persists: Get medical help.

P342 + P316 If experiencing respiratory symptoms: Get emer-

gency medical help immediately.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

P391 Collect spillage.

Storage:

P403 Store in a well-ventilated place.

P405 Store locked up.

Disposal:

according to the Globally Harmonized System



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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.

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
Procaine hydrochloride	51-05-8	>= 1 - < 5
Chlorphenamine hydrogen maleate	113-92-8	>= 1 - < 3
Dexamethasone	50-02-2	>= 0.025 - < 0.1

4. FIRST AID MEASURES

In the case of accident or if you feel unwell, seek medical ad-General advice

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

> If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

May cause an allergic skin reaction.

Never give anything by mouth to an unconscious person.

Most important symptoms

Harmful if swallowed.

and effects, both acute and

Causes serious eye irritation.

delayed

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May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Suspected of damaging the unborn child.

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

tive airways dysfunction syndrome).

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

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

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam 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)

Sulphur 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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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 pro-

tective 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

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cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. 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 as-

sessment

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 respira-

tory 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.

Conditions for safe storage : Keep in properly labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	

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Dihydrostreptomycin sulphate	5490-27-7	TWA	OEB 2 (>= 100 < 1000 μg/m3)	Internal	
		TWA	0.4 mg/m3	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 ²	Internal	

Engineering measures : Use appropriate engineering controls and manufacturing

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

quick connections).

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

protect products, workers, and the environment.

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

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended 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.

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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.

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

Partition coefficient: n-

octanol/water

Not applicable

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Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

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

Molecular weight No data available

Particle characteristics

Particle size Not applicable

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

products

: No hazardous decomposition products are known.

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

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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:

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

No skin irritation Result

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

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Dexamethasone:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

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

Components:

Dihydrostreptomycin sulphate:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitisation in humans

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

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitisation in humans

Assessment : Probability of respiratory sensitisation in humans based on

animal testing

Chlorphenamine hydrogen maleate:

Exposure routes : Dermal

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Procaine hydrochloride:

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

Result: negative

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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

Test Type: in vitro assay

Test system: mouse lymphoma cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Chlorphenamine hydrogen maleate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 30 - 60 mg/kg body weight

Result : negative

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

NOAEL : 20 - 50 mg/kg body weight

Result : negative

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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 foetal development

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse Application Route: Oral

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

observed.

Remarks: The significance of these findings for humans is not

certain.

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

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

Dexamethasone:

Effects on foetal develop-

ment

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

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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

Not classified based on available information.

Components:

Chlorphenamine hydrogen maleate:

Target Organs : Cardio-vascular system

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Dexamethasone:

Exposure routes : Ora

Target Organs : Adrenal gland, Immune system, thymus gland

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Chlorphenamine hydrogen maleate:

Species : Rat

NOAEL : 10 mg/kg

Application Route : Oral

Exposure time : 6 Weeks

Remarks : No significant adverse effects were reported

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

Dexamethasone:

Species : Rat

NOAEL : 0.0015 mg/kg

Application Route : Oral

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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 toxi

Remarks : Significant toxicity observed in testing

Species : Rat
LOAEL : 0.4 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Immune system

Remarks : Significant toxicity observed in testing

Species : Dog
LOAEL : 8 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Immune system

Remarks : Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Dihydrostreptomycin sulphate:

General Information : Target Organs: ear Symptoms: hearing loss

Chlorphenamine hydrogen maleate:

Inhalation : Symptoms: central nervous system effects

Remarks: May cause respiratory tract irritation.

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

Remarks: May cause irreversible eye damage. Symptoms: central nervous system effects

Remarks: Based on Human Evidence

Dexamethasone:

Ingestion

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Target Organs: Immune system Ingestion

Target Organs: Adrenal gland

Target Organs: Bone

Symptoms: muscle weakness

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

plants

: EC50: > 0.01 - 0.1 mg/l

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox- : 10

M-Factor (Chronic aquatic

toxicity)

: 10

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

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

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:

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

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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

EC50: > 1,000 mg/lToxicity to microorganisms

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.033 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

M-Factor (Chronic aquatic

toxicity)

Persistence and degradability

Components:

Dexamethasone:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 3.54 d

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Dihydrostreptomycin sulphate:

Bioaccumulation Species: Fish

Bioconcentration factor (BCF): 3.16

Partition coefficient: n- : log Pow: -7.51

octanol/water

Procaine hydrochloride:

Partition coefficient: n-

octanol/water

: log Pow: 1.389

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Dexamethasone:

Partition coefficient: n-

octanol/water

log Pow: 1.83

Mobility in soil

No data available

Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

964

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

according to the Globally Harmonized System



Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 3.0
 28.09.2024
 5491617-00012
 Date of first issue: 10.03.2020

Packing group : III Labels : 9

EmS Code : F-A, S-F Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 28.09.2024

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 Agen

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Sheet cy, 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 con-

according to the Globally Harmonized System



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centration; 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

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

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