SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Supplier's company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary medicine

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Acute toxicity (Oral) : Category 4
Serious eye damage/eye irritation : Category 2
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

GHS label elements
Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.
                  H317 May cause an allergic skin reaction.
**Precautionary statements:**

**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing 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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.

**Response:**
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

**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.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 50 - &lt; 60</td>
<td></td>
</tr>
<tr>
<td>2-(4-Aminobenzo-yloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>6130-64-9</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Chlorphenamine hydrogen maleate</td>
<td>113-92-8</td>
<td>&gt;= 1 - &lt; 3</td>
<td></td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
</tr>
</tbody>
</table>

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: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides
Chlorine compounds
Metal oxides

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.

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

Environmental precautions: Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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

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 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.

Avoidance of contact:
Oxidizing agents

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.

Storage
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

Packaging material:
Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration /</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
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</table>
### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state**: suspension
Colour : white
Odour : No data available
Odour Threshold : No data available
Melting point/freezing point : No data available
Boiling point, initial boiling point and boiling range : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : Not applicable
Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Flash point : No data available
Decomposition temperature : No data available
pH : 5.0 - 6.0
Evaporation rate : No data available
Auto-ignition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Density and / or relative density
Relative density : No data available
Density : 1.17 - 1.21 g/cm³
Relative vapour density : 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.

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.

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: 662.58 mg/kg
  Method: Calculation method
- Acute dermal toxicity: Acute toxicity estimate: > 2,000 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)ethylidethylammonium (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 oral toxicity : LD50 (Rat): 118 - 306 mg/kg
         : LD50 (Mouse): 130 mg/kg
Acute inhalation toxicity : LC50 (Rat): 0.61 mg/l
         : Exposure time: 4 h
                 : Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rat): 365 mg/kg
Acute toxicity (other routes of administration) : LD50 (Rat): 89 mg/kg
Dexamethasone:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
         : LD50 (Mouse): > 6,500 mg/kg
Acute toxicity (other routes of administration) : LD50 (Rat): 14 mg/kg
         : Application Route: Subcutaneous

Skin corrosion/irritation
Not classified based on available information.

Components:
2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:
Result : No skin irritation

Chlorphenamine hydrogen maleate:
Species : Rabbit
Result : No skin irritation

Dexamethasone:
Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:
Result : No eye irritation

Chlorphenamine hydrogen maleate:
Species : Rabbit
Result : Severe irritation
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)ethyl-diethylammonium (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

Chlorphenamine hydrogen maleate:
Exposure routes: Dermal
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:
Procaine hydrochloride:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials
Chlorphenamine hydrochloride maleate:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Mouse Lymphoma
  Result: negative
- Test Type: Sister chromatid exchange assay
  Test system: Chinese hamster ovary cells
  Result: positive
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Test system: Rat hepatocytes
  Result: negative

Germ cell mutagenicity:
- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Dexamethasone:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro assay
  Test system: Mouse lymphoma cells
  Result: negative

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

Carcinogenicity:
Not classified based on available information.

Components:

Chlorphenamine hydrochloride maleate:
- Species: Rat
- Application Route: Oral
- Exposure time: 2 Years
- NOAEL: 30 - 60 mg/kg body weight
- Result: negative

- Species: Mouse
- Application Route: Oral
- Exposure time: 2 Years
- NOAEL: 20 - 50 mg/kg body weight
- Result: negative

Reproductive toxicity:
Suspected of damaging the unborn child.
Components:

Dihydrostreptomycin sulphate:
Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.

Chlorphenamine hydrogen maleate:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 20 mg/kg body weight
Result: No effects on fertility, No effects on foetal development

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 20 mg/kg body weight
Result: Reduced embryonic survival, No malformations were observed.
Remarks: The significance of these findings for humans is not certain.

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, Retardations

Reproductive toxicity - Assessment: May damage the unborn child.
STOT - single exposure
Not classified based on available information.

Components:

Chlorphenamine hydrogen maleate:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Components:

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

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

Repeated dose toxicity

Components:

Chlorphenamine hydrogen maleate:
Species: Rat
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Remarks: No significant adverse effects were reported

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

Dexamethasone:
Species: Rat
NOAEL: 0.0015 mg/kg
Application Route: Oral
Exposure time: 7 d
Target Organs: Liver
Remarks: Significant toxicity observed in testing

Species: Rat
LOAEL: 0.003 mg/kg
Application Route: Oral
Exposure time : 90 d  
Target Organs : Blood, Adrenal gland, thymus gland  
Remarks : Significant toxicity observed in testing  

Species : Rat  
LOAEL : 0.125 mg/kg  
Application Route : Oral  
Exposure time : 6 Weeks  
Target Organs : Adrenal gland  
Remarks : Significant toxicity observed in testing  

Species : Rat  
LOAEL : 0.4 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Immune system  
Remarks : Significant toxicity observed in testing  

Species : Dog  
LOAEL : 8 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Immune system  
Remarks : Significant toxicity observed in testing

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Dihydrostreptomycin sulphate:
General Information : Target Organs: ear  
Symptoms: hearing loss

Chlorphenamine hydrogen maleate:
Inhalation : Symptoms: central nervous system effects  
Remarks: May cause respiratory tract irritation.  

Skin contact : Remarks: May irritate skin.  

Eye contact : Symptoms: Eye irritation  
Remarks: May cause irreversible eye damage.  

Ingestion : Symptoms: central nervous system effects  
Remarks: Based on Human Evidence

Dexamethasone:
Ingestion : Target Organs: Immune system  
Target Organs: Adrenal gland
Target Organs: Bone
Symptoms: muscle weakness

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 toxicity) : 10
M-Factor (Chronic aquatic toxicity) : 10

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

Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

Procaine hydrochloride:

Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

Dexamethasone:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 56 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity):
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:
Dihydrostreptomycin sulphate:
Bioaccumulation:
Species: Fish
Bioconcentration factor (BCF): 3.16

Partition coefficient: n-octanol/water:
log Pow: -7.51

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

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

Mobility in soil
No data available
Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: 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.

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

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): 964
- Packing instruction (passenger aircraft): 964
- Environmentally hazardous: yes

IMDG-Code
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.
National Regulations
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd
SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.3  Revision Date: 2021/08/27  SDS Number: 5491618-00004  Date of last issue: 2020/10/10
Date of first issue: 2020/03/10

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

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 storing, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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