according to GB/T 16483 and GB/T 17519



# Amiloride / Hydrochlorothiazide Formulation

Version Revision Date: SDS Number: Date of last issue: 2022/10/01 2023/04/04 42680-00018 Date of first issue: 2015/01/05 6.0

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amiloride / Hydrochlorothiazide Formulation

Manufacturer or supplier's details

Company

199 Wenhai North Road Address

HEDA, Hangzhou - Zhejiang Province - CHINA 310018

908-740-4000 Telephone

Emergency telephone number: 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical

Restrictions on use

Not applicable

#### 2. HAZARDS IDENTIFICATION

#### **Emergency Overview**

**Appearance** powder Colour pale red-brown Odour odourless

Harmful if swallowed. Causes damage to organs through prolonged or repeated exposure.

**GHS Classification** 

Acute toxicity (Oral) : Category 4

Specific target organ toxicity - : Category 1

repeated exposure

**GHS** label elements

Hazard pictograms

Signal word

Hazard statements H302 Harmful if swallowed.

H372 Causes damage to organs through prolonged or repeated

exposure.

according to GB/T 16483 and GB/T 17519



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Precautionary statements : Prevention:

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth. P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Physical and chemical hazards

Not classified based on available information.

#### Health hazards

Harmful if swallowed. Causes damage to organs through prolonged or repeated exposure.

#### **Environmental hazards**

Not classified based on available information.

## Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Hydrochlorothiazide	58-93-5	>= 20 -< 30
Starch	9005-25-8	>= 10 -< 20
Amiloride	17440-83-4	>= 1 -< 2.5

# 4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

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

of water.

Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do

according to GB/T 16483 and GB/T 17519



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so by medical personnel. Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Contact with dust can cause mechanical irritation or drying of

Most important symptoms and effects, both acute and delayed

the skin

the skin.

Dust contact with the eyes can lead to mechanical irritation.

Harmful if swallowed.

Causes damage to organs through prolonged or repeated

exposure.

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 None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Chlorine compounds Sulphur oxides Metal oxides

Oxides of phosphorus

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. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

according to GB/T 16483 and GB/T 17519



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cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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

Handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres. Use only with adequate ventilation.

Local/Total ventilation

Advice on safe handling : Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

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

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. 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

Storage

Conditions for safe storage : Keep in properly labelled containers.

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

## Components with workplace control parameters

according to GB/T 16483 and GB/T 17519



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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Hydrochlorothiazide	58-93-5	TWA	100 µg/m3 (OEB 2)	Internal
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Amiloride	17440-83-4	TWA	100 μg/m3	Internal

**Engineering measures**: Use feasible engineering controls to minimize exposure to

compound.

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

protect products, workers, and the environment.

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 : Particulates type

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.

Skin and body protection

Hand protection

: Work uniform or laboratory coat.

Material : Chemical-resistant gloves

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

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke. 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 : powder

Colour : pale red-brown

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

according to GB/T 16483 and GB/T 17519



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Initial boiling point and boiling:

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

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 : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : 302.10 g/mol

Particle size : No data available

## 10. STABILITY AND REACTIVITY

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

according to GB/T 16483 and GB/T 17519



# Amiloride / Hydrochlorothiazide Formulation

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Possibility of hazardous reac- :

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

: No hazardous decomposition products are known.

# 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1,785 mg/kg

Method: Calculation method

#### **Components:**

Hydrochlorothiazide:

Acute oral toxicity : LD50 (Rat): > 2,750 mg/kg

LD50 (Mouse): > 2,830 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 990 mg/kg

Application Route: Intravenous

LD50 (Mouse): 590 mg/kg Application Route: Intravenous

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Amiloride:

Acute oral toxicity : LD50 (Mouse): 56 mg/kg

LD50 (Rat): > 150 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

#### Hydrochlorothiazide:

according to GB/T 16483 and GB/T 17519



# Amiloride / Hydrochlorothiazide Formulation

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Species : Rabbit

Result : No skin irritation

Amiloride:

Species : Rabbit

Result : Mild skin irritation Remarks : slight irritation

# Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

## Hydrochlorothiazide:

Species : Rabbit

Result : Mild eye irritation

Starch:

Species : Rabbit

Result : No eye irritation

Amiloride:

Species : Rabbit

Remarks : Severe eye irritation

## Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### Starch:

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

# Germ cell mutagenicity

Not classified based on available information.

## **Components:**

#### Hydrochlorothiazide:

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

Result: negative

Test Type: Chromosomal aberration

according to GB/T 16483 and GB/T 17519



# Amiloride / Hydrochlorothiazide Formulation

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Test system: Chinese hamster ovary cells

Result: negative

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: positive

Test Type: in vitro assay

Test system: mouse lymphoma cells

Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Chinese hamster Cell type: Bone marrow

Result: negative

Test Type: in vivo assay

Species: Mouse

Cell type: Bone marrow

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Starch:

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

Result: negative

Amiloride:

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

Result: negative

#### Carcinogenicity

Not classified based on available information.

## **Components:**

## Hydrochlorothiazide:

Species : Mouse, female

Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse, male

Application Route : Oral
Exposure time : 2 Years
Result : equivocal

Species : Rat, male and female

Application Route : Oral
Exposure time : 2 Years
Result : negative

according to GB/T 16483 and GB/T 17519



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Amiloride:

Species Rat Application Route Oral Exposure time 92 weeks

10 mg/kg bw/day

Result negative

Species Mouse Application Route Oral 104 weeks Exposure time 8 mg/kg bw/day

Result negative

Reproductive toxicity

Not classified based on available information.

**Components:** 

Hydrochlorothiazide:

Effects on fertility Test Type: Fertility

> Species: Rat, male and female Application Route: oral (feed)

Fertility: NOAEL: 4 mg/kg body weight

Result: Effects on fertility

Test Type: Fertility

Species: Mouse, male and female Application Route: oral (feed)

Fertility: NOAEL: 100 mg/kg body weight

Result: Effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 3,000 mg/kg body weight

Result: No teratogenic effects

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 1,000 mg/kg body weight

Result: No teratogenic effects

Amiloride:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

Result: No effects on fertility and early embryonic develop-

ment were detected.

Test Type: Embryo-foetal development

according to GB/T 16483 and GB/T 17519



# Amiloride / Hydrochlorothiazide Formulation

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Species: Mouse

Application Route: Oral

Result: No effects on fertility and early embryonic develop-

ment were detected.

## STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

#### **Components:**

#### Hydrochlorothiazide:

Target Organs : Kidney, Parathyroid gland

Assessment : Causes damage to organs through prolonged or repeated

exposure.

# Repeated dose toxicity

#### **Components:**

#### Hydrochlorothiazide:

Species : Rat, male and female

LOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 2 yr

Target Organs : Kidney, Parathyroid gland

Species : Mouse, male and female

NOAEL : 300 - 550 mg/kg

Application Route : Oral Exposure time : 2 yr

Remarks : No significant adverse effects were reported

Species : Dog

: 50 - 200 mg/kg

Application Route : Oral Exposure time : 9 Months

Target Organs : Parathyroid gland

#### Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

# **Aspiration toxicity**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### **Components:**

## Hydrochlorothiazide:

No aspiration toxicity classification

# Experience with human exposure

# **Components:**

# Hydrochlorothiazide:

Symptoms: Eye irritation Eye contact

Symptoms: Dizziness, Headache, Fatigue, Nausea, Ab-Ingestion

dominal pain, hypotension, dry mouth, electrolyte imbalance,

eve pain

Amiloride:

Ingestion Symptoms: hyperkalemia

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

#### **Components:**

#### Hydrochlorothiazide:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

#### Amiloride:

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 56.3 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

## Persistence and degradability

## **Components:**

## Hydrochlorothiazide:

Stability in water Hydrolysis: 46.2 %(96 h)

#### Bioaccumulative potential

No data available

#### Mobility in soil

No data available

# Other adverse effects

No data available

according to GB/T 16483 and GB/T 17519



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#### 13. DISPOSAL CONSIDERATIONS

## **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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 : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

#### IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

#### **IMDG-Code**

UN number Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Not applicable Labels **EmS Code** Not applicable Not applicable Marine pollutant

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

Not applicable for product as supplied.

#### **National Regulations**

#### GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable

according to GB/T 16483 and GB/T 17519



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Labels : Not applicable

Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

# National regulatory information Law on the Prevention and Control of Occupational Diseases

## **Yangtze River Protection Law**

This product does not contain any dangerous chemicals prohibited for inland river transport.

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 : 2023/04/04

**Further information** 

Sources of key data used to : compile the Safety Data

compile the Safety Data
Sheet

Managarahan ahan sa haya haya

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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 : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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 Or-

according to GB/T 16483 and GB/T 17519



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ganisation 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

#### Disclaimer

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.

CN/EN