

# Amiloride / Hydrochlorothiazide Formulation

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 44151-00019 Date of first issue: 05.01.2015 6.0 04.04.2023

#### 1. PRODUCT AND COMPANY IDENTIFICATION

: Amiloride / Hydrochlorothiazide Formulation Product name

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 Pharmaceutical

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

repeated exposure

Specific target organ toxicity - : Category 1 (Kidney, Parathyroid gland)

**GHS** label elements

Hazard pictograms

Signal word

H302 Harmful if swallowed. Hazard statements

H372 Causes damage to organs (Kidney, Parathyroid gland)

through prolonged or repeated exposure.

Precautionary statements **Prevention:** 

P260 Do not breathe dust.



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P264 Wash skin thoroughly after handling.

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

Response:

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

Rinse mouth.

P319 Get medical help if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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

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

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

and effects, both acute and

delayed

Most important symptoms

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



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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

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 protective 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

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container 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.



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Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

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 eves.

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.

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

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

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



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Hand protection

Material : Chemical-resistant gloves

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.

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. 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

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



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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.

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

: Oxidizing agents

No hazardous decomposition products are known.

products

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

**Acute toxicity** 

Harmful if swallowed.

**Product:** 



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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:

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



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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 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 - : Weight of evidence does not support classification as a germ



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Assessment 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

Amiloride:

Species : Rat
Application Route : Oral
Exposure time : 92 weeks

10 mg/kg bw/day

Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 104 weeks

: 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



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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

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 (Kidney, Parathyroid gland) 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



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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.

**Components:** 

Hydrochlorothiazide:

No aspiration toxicity classification

**Experience with human exposure** 

**Components:** 

Hydrochlorothiazide:

Eye contact : Symptoms: Eye irritation

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

dominal pain, hypotension, dry mouth, electrolyte imbalance,

eye 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



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Toxicity to daphnia and other:

aquatic invertebrates

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

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** 

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable



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#### 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 : 04.04.2023

Further information

Sources of key data used to compile the Safety Data

compile the Safety Data Sheet Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

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 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 Substanc-



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es; (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.

IN / EN