SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Amiloride / Hydrochlorothiazide Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD Innishannon County Cork - Ireland
   Telephone : 353 214329300
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 1
   H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H372 Causes damage to organs through prolonged or repeated exposure.
   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.
Amiloride / Hydrochlorothiazide Formulation

Response:
P314  Get medical advice/attention if you feel unwell.

Hazardous components which must be listed on the label:
Hydrochlorothiazide

2.3 Other hazards
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>200-403-3</td>
<td>5-89-3</td>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>200-403-3</td>
<td>STOT RE 1; H372</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Amiloride</td>
<td>17440-83-4</td>
<td>200-403-3</td>
<td>5-89-3</td>
<td>Amiloride</td>
<td>17440-83-4</td>
<td>200-403-3</td>
<td>Acute Tox. 2; H300 Eye Irrit. 2; H319 Aquatic Chronic 3; H412</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes damage to organs through prolonged or repeated exposure.

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

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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 products: Carbon oxides
Nitrogen oxides (NOx)
Chlorine compounds
Sulphur oxides
Metal oxides
Oxides of phosphorus

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
Environmental precautions: Discharge into the environment must be avoided. 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.

6.3 Methods and material for containment and cleaning up
Methods for 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 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.

### 7.2 Conditions for safe storage, including any incompatibilities

**Requirements for storage areas and containers:**
- Keep in properly labelled containers. Store in accordance with the particular national regulations.

**Advice on common storage:**
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

### 7.3 Specific end use(s)

**Specific use(s):**
- No data available

---

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

**Further information:**
Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhaleable dust)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

**Amiloride** | 17440-83-4 | TWA                           | 100 µg/m³                     | Internal  |

### 8.2 Exposure controls

**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**

**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.

**Hand protection**

Material: Chemical-resistant gloves

**Skin and body protection**

: Work uniform or laboratory coat.

**Respiratory protection**

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

Filter type: Particulates type (P)

### SECTION 9: Physical and chemical properties

**9.1 Information on basic 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, handling or other means.

**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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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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.

9.2 Other information

Flammability (liquids): No data available
Molecular weight: 302.10 g/mol
Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials

Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

**Acute toxicity**
Not classified based on available information.

**Product:**
- Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
- Method: Calculation method

**Components:**

**Hydrochlorothiazide:**
- Acute oral toxicity: LD50 (Rat): 10,000 mg/kg
- LD50 (Mouse): 10,000 mg/kg
- Acute toxicity (other routes of administration): LD50 (Rat): 990 mg/kg
  - Application Route: Intravenous
- LD50 (Dog): 250 mg/kg
  - Application Route: Intravenous

**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
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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.

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

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  
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 development: Test Type: Development
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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 development: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Result: No effects on fertility and early embryonic development were detected.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Result: No effects on fertility and early embryonic development 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
**Amiloride / Hydrochlorothiazide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2</td>
<td>09/13/2019</td>
<td>44150-00013</td>
<td>24.04.2019</td>
<td>05.01.2015</td>
</tr>
</tbody>
</table>

**Species**: Dog 50 - 200 mg/kg

**Application Route**: Oral

**Exposure time**: 9 Months

**Target Organs**: Parathyroid gland

**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, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

**Amiloride**:
- **Ingestion**
  - Symptoms: hyperkalemia

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components**:

**Hydrochlorothiazide**:
- **Toxicity to fish**
  - LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l
  - Exposure time: 96 h
- **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

**12.2 Persistence and degradability**

**Components**:

**Hydrochlorothiazide**:
- **Stability in water**
  - Hydrolysis: 46.2 % (96 h)
12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- **Product**: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
- **Remarks**: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- **REACH - Candidate List of Substances of Very High**: Not applicable
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Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation
(Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that de-
plete the ozone layer: Not applicable

Regulation (EC) No 850/2004 on persistent organic pol-
lutants: Not applicable

Regulation (EC) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import
of dangerous chemicals:

REACH - Restrictions on the manufacture, placing on
the market and use of certain dangerous substances,
preparations and articles (Annex XVII):

major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national
regulations, where applicable.

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

AICS: not determined

DSL: not determined

IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Full text of H-Statements

H300: Fatal if swallowed.
H319: Causes serious eye irritation.
H372: Causes damage to organs through prolonged or repeated
exposure.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Irrit.: Eye irritation
STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure
  Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
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SDS Number: 44150-00013
Date of last issue: 24.04.2019
Date of first issue: 05.01.2015

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Road; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
STOT RE 1
H372

Classification procedure:
Calculation method

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.
Amiloride / Hydrochlorothiazide Formulation

Version 4.2  Revision Date: 09/13/2019  SDS Number: 44150-00013  Date of last issue: 24.04.2019  Date of first issue: 05.01.2015