

# Spironolactonum micronisatum

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 01/06/2013 Revision date: 09/02/2017

**853054**

Version: 2.0

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

### 1.1. Product identifier

Product form : Substance  
Trade name : Spironolactonum micronisatum  
EC No : 200-133-6  
CAS No : 52-01-7  
Product code : 853054  
Product group : Raw material

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical  
Industrial/Professional use spec : Industrial  
For professional use only

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

Duchefa Farma BV  
A. Hofmanweg 71  
2031BH Haarlem - Nederland  
T +31(0)23-5319093  
[farma@ducheffa.nl](mailto:farma@ducheffa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
+31(0)23-5319093 (M-F 09:00-17:00)  
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Carcinogenicity, Category 2 H351  
Reproductive toxicity, Category 1B H360

Full text of hazard classes and H-statements : see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)

:



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H351 - Suspected of causing cancer (in contact with skin, if inhaled, if swallowed)  
H360 - May damage fertility. May damage the unborn child (in contact with skin, if inhaled, if swallowed)

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type

: Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Spironolactone micronized	(CAS No) 52-01-7 (EC No) 200-133-6	100	Carc. 2, H351 Repr. 1B, H360

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general

: Never give anything by mouth to an unconscious person. Suspected of causing cancer. IF exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation

: Assure fresh air breathing. Allow the victim to rest. Call a POISON CENTER or doctor/physician.

First-aid measures after skin contact

: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact

: Rinse immediately with plenty of water. Get medical advice/attention.

First-aid measures after ingestion

: Rinse mouth. Induce vomiting. Give water to drink. Obtain emergency medical attention.

## 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : May damage fertility. May damage the unborn child.

## 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Combustible. In case of fire, corrosive and harmful gases come free.

### 5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust.

#### 6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

### 6.4. Reference to other sections

Reference to other sections (8, 13).

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

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

Storage conditions	: Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage temperature	: 15 - 25 °C

## 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Personal protective equipment:

Avoid all unnecessary exposure.

#### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

#### Eye protection:

Chemical goggles or safety glasses

#### Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

#### Respiratory protection:

Dustmask with filtertype P1

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White. yellowish.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: 7
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 198 - 207 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available

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Decomposition temperature	: No data available
Flammability (solid, gas)	: Combustible
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Insoluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Dust may form explosive mixture in air.
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Not established.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Oxidizing agents.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Spironolactonum micronisatum (52-01-7)	
LD50 oral rat	> 1 mg/kg
Oral, Mouse LD50	1 gm/kg
Oral, rabbit LD50	1 gm/kg

Skin corrosion/irritation : Not classified  
pH: 7

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified  
pH: 7

Additional information : Based on available data, the classification criteria are not met

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Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
	Based on available data, the classification criteria are not met
Carcinogenicity	: Suspected of causing cancer (in contact with skin, if inhaled, if swallowed).
Additional information	: Suspected of causing cancer (May cause cancer by inhalation)
Reproductive toxicity	: May damage fertility. May damage the unborn child (in contact with skin, if inhaled, if swallowed).
Additional information	: May damage fertility or the unborn child
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.
IARC group	: 3
Other information	: ACGIH: A4 - Not Classifiable as a Human Carcinogen, California: carcinogen; initial date 5/1/97, NIOSH: potential occupational carcinogen, NTP: Known carcinogen (listed as ** undefined **), OSHA: Select carcinogen.

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

Spironolactonum micronisatum (52-01-7)	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Spironolactonum micronisatum (52-01-7)	
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: wastes from the MFSU of pharmaceuticals.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

#### 14.6. Special precautions for user

##### - Overland transport

No data available

##### - Air transport

No data available

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### SECTION 15: Regulatory information

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

##### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Spironolactonum micronisatum is not on the REACH Candidate List

Spironolactonum micronisatum is not on the REACH Annex XIV List

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete

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8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)

### Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
LD50	Median lethal dose

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : REACH Disclaimer:  
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

### Full text of H- and EUH-statements:

Carc. 2	Carcinogenicity, Category 2
Repr. 1B	Reproductive toxicity, Category 1B
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child

SDS EU (REACH Annex II) Version 2017

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