

## 1: Identification

- **1.1 Product identifier**
- **Trade name:** Spironolactone  
Spironolactonum
- **Product Code:** 101043
- **CAS Number:**  
52-01-7
- **EC number:**  
200-133-6
- **1.2 Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **1.4 Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

## 2: Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 Health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** The substance is classified and labeled according to the CLP regulation.
- **Hazard pictograms** GHS08
- **Signal word** Warning
- **Hazard statements**  
H361 Suspected of damaging fertility or the unborn child.
- **Precautionary statements**  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**
- **HMIS-ratings (scale 0 - 4)**
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3: Composition/information on ingredients

- **3.1 Chemical characterization: Substances**
- **CAS No. Description**  
52-01-7 Spironolactone  
Spironolactonum
- **Identification number(s)**
- **EC number:** 200-133-6

## 4: First-aid measures

- **4.1 Description of first aid measures**
- **General information:**  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**  
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:** Seek medical treatment.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
Immediately call a doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

## 5: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Water spray  
Carbon dioxide  
Fire-extinguishing powder  
Alcohol resistant foam
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
Sulphur dioxide (SO<sub>2</sub>)

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- Carbon monoxide (CO)
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.  
Mouth respiratory protective device.
- **Additional information** Cool endangered receptacles with water spray.

## 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Ensure adequate ventilation
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 7: Handling and storage

- **7.1 Precautions for safe handling**  
Thorough dedusting.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.
- **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

## 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Be sure to clean skin thoroughly after work and before breaks.

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Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Not required.

· **Body protection:** Protective work clothing

## 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Powder
· <b>Color:</b>	Whitish
· <b>Odor:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/Melting range:</b>	198-207 °C (388-405 °F)
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Not determined.

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|---|---|
| · <b>Danger of explosion:</b>                     | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                        |   |
| Lower:  | Not determined.                               |
| Upper:  | Not determined.                               |
| · <b>Vapor pressure:</b>                          | Not applicable.                               |
| · <b>Density:</b>                                 | Not determined.                               |
| · <b>Relative density</b>                         | Not determined.                               |
| · <b>Vapour density</b>                           | Not applicable.                               |
| · <b>Evaporation rate</b>                         | Not applicable.                               |
| · <b>Solubility in / Miscibility with Water:</b>  | Insoluble.                                    |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                               |
| · <b>Viscosity:</b>                               |   |
| Dynamic:  | Not applicable.                               |
| Kinematic:  | Not applicable.                               |
| · <b>9.2 Other information</b>                    | No further relevant information available.    |

## 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**
  - Reacts with strong acids.
  - Reacts with oxidizing agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
  - Carbon monoxide and carbon dioxide
  - Sulfur oxides (SO<sub>x</sub>)

## 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**

Oral	LD50	> 1000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

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- **Additional toxicological information:**
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

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- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

## 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**  
Must be specially treated adhering to official regulations.  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14: Transport information

- **14.1 UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void
- **14.2 UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Void

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· <b>14.3 Transport hazard class(es)</b>	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· <b>14.4 Packing group</b>	
· DOT, ADR, IMDG, IATA	Void
· <b>14.5 Environmental hazards:</b>	
· Marine pollutant:	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Not dangerous according to the above specifications.
· <b>UN "Model Regulation":</b>	-

## 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16: Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

- **Relevant phrases**  
R 20/21/22-40  
S 22-36
- **Department issuing SDS:**  
Fagron US  
Quality Assurance
- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 10/21/2015 / 16
- **Abbreviations and acronyms:**  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
ICAO: International Civil Aviation Organisation  
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods

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IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
Repr. 2: Reproductive toxicity, Hazard Category 2

· **\* Data compared to the previous version altered.**

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