



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Potassium Canrenoate for Injection

**Trade Name:** Soldactone; Soludactone  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as diuretic.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Potassium Canrenoate	2181-04-6	218-554-9	95

Ingredient	CAS Number	EU EINECS List	%
Water for injection	7732-18-5	231-791-2	*
Tromethamine	77-86-1	201-064-4	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Light yellow powder (lyophilised).  
**Signal Word:** WARNING

**Statement of Hazard:** Harmful if swallowed.  
Suspected of causing cancer.  
Suspected of damaging the unborn child.  
May cause harm to breastfed babies.

### Additional Hazard Information:

**Short Term:** No data available: eye, skin.  
**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include changes in electrolytes, nausea, chills, blue appearance (cyanosis), decrease in blood pressure (hypotension), breast development in males (gynecomastia), and gastrointestinal disturbances. Secreted in human breast milk.

**EU Indication of danger:** Carcinogenic: Category 3  
Toxic to Reproduction; Category 3  
Harmful

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### EU Hazard Symbols:



### EU Risk Phrases:

R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect.  
R63 - Possible risk of harm to the unborn child.  
R64 - May cause harm to breastfed babies.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 7. HANDLING AND STORAGE

**General Handling:** Avoid generating airborne dust. Avoid inhalation and contact with skin, eye, and clothing. Use adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8).

**Storage Conditions:** Store at controlled room temperature. Protect from light.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Lyophilized powder	<b>Color:</b>	Light yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Light  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

#### Potassium Canrenoate

Rat	Oral	LD50	650 mg/kg
Rat	Intraperitoneal	LD50	183 mg/kg
Rat	Intravenous	LD50	112 mg/kg
Mouse	Oral	LD50	740 mg/kg
Mouse	Intravenous	LD50	125 mg/kg

#### Tromethamine

Rat	Oral	LD50	5900 mg/kg
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### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Potassium Canrenoate

6 Month(s) Rat Oral 10 mg/kg/day NOEL None identified

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Potassium Canrenoate

Fertility and Embryonic Development	Rabbit	Oral	60 mg/kg	LOAEL	Fetotoxicity
Embryo / Fetal Development	Mouse	Intraperitoneal	420 mg/kg	LOAEL	Fetotoxicity
Reproductive & Fertility	Rat	Intravenous	100 mg/kg	NOAEL	No effects at maximum dose
Reproductive & Fertility	Rabbit	Intravenous	50 mg/kg	NOAEL	Negative, Not Teratogenic
Embryo / Fetal Development	Mouse	Intraperitoneal	80 mg/kg	LOAEL	Fetotoxicity

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Potassium Canrenoate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Fungi		Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Not specified	Positive
<i>In Vivo</i>	Not specified	Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Potassium Canrenoate

2 Year(s)	Rat	Oral, in feed	50 mg/kg/day	LOAEL	Tumors, Blood forming organs
1 Year(s)	Rat	Oral, in feed	90 mg/kg/day	LOAEL	Blood forming organs
4 Year(s)	Non-human Primate	Oral	60 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Rat	Oral	270 mg/kg/day	LOAEL	Tumors

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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## 15. REGULATORY INFORMATION

**EU Symbol:** Xn  
**EU Indication of danger:** Carcinogenic: Category 3  
Toxic to Reproduction; Category 3  
Harmful

**EU Risk Phrases:**  
R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect.  
R63 - Possible risk of harm to the unborn child.  
R64 - May cause harm to breastfed babies.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
WARNING  
Harmful if swallowed.  
Suspected of causing cancer.  
Suspected of damaging the unborn child.  
May cause harm to breastfed babies.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
D2a very toxic materials  
D2b toxic materials



**Potassium Canrenoate**  
EU EINECS List 218-554-9

**Water for injection**  
Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 231-791-2

**Tromethamine**  
Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
Standard for the Uniform Scheduling  
for Drugs and Poisons: Schedule 4  
EU EINECS List 201-064-4

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### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**