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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium Canrenoate</td>
<td>2181-04-6</td>
<td>218-554-9</td>
<td>95</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Tromethamine</td>
<td>77-86-1</td>
<td>201-064-4</td>
<td>*</td>
</tr>
</tbody>
</table>

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
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.
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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Lyophilized powder</th>
<th>Color:</th>
<th>Light yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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
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) Salmonella, E. coli Negative
In Vitro Fungi Negative
In Vitro Mammalian Cell Mutagenicity Not specified Positive
In Vivo 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.
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
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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

End of Safety Data Sheet