1. Identification

Product identifier Ropivacaine Related Compound A

Other means of identification

- Catalog number 1605512
- CAS number 21436-98-6
- Synonyms 2,6-Xylidine hydrochloride
- Chemical name 2,6-Dimethylaniline hydrochloride

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

- Company name U. S. Pharmacopeia
- Address 12601 Twinbrook Parkway
- Rockville
- MD
- 20852-1790

Website www.usp.org

Telephone RS Technical Services 301-816-8129

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US &
Canada 1-800-424-9300
CHEMTREC outside US &
Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Carcinogenicity Category 2

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement Suspected of causing cancer.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

Response If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

Material name: Ropivacaine Related Compound A

1605512 Version #: 04 Revision date: 10-23-2018 Issue date: 07-08-2005
4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed**
Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects. Methemoglobinemia.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire fighting equipment/instructions**
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials. Cool containers exposed to flames with water until well after the fire is out.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions**
Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. No special environmental precautions required.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Occupational exposure limits**
No exposure limits noted for ingredient(s).

**Biological limit values**
No biological exposure limits noted for the ingredient(s).
Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection**

**Hand protection**
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.

**Other**
Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

**Respiratory protection**
Choose respiratory protection appropriate to the task and the level of existing engineering controls. Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup.

**Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**
Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. Pharmacological effects may be seen with occupational exposure.

**9. Physical and chemical properties**

**Appearance**
Appearance descriptions are general information and not specific to any USP lot.

**Physical state**
Solid.

**Form**
Crystalline powder.

**Color**
White.

**Odor**
Not available.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
Not available.

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)**
Not available.

**Flammability limit - upper (%)**
Not available.

**Explosive limit - lower (%)**
Not available.

**Explosive limit - upper (%)**
Not available.

**Vapor pressure**
0.02 kPa at 25 °C

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility(ies)**
**Solubility (water)**
Not available.

**Solubility (other)**
Methanol: Slightly soluble.
Dimethyl sulfoxide: Slightly soluble.

**Auto-ignition temperature**
Not available.

**Decomposition temperature**
Not available.

**Viscosity**
Not available.
Other information

- **Molecular formula**: C8H11N . HCl
- **Molecular weight**: 157.64

10. Stability and reactivity

**Reactivity**
The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability**
Material is stable under normal conditions.

**Possibility of hazardous reactions**
No dangerous reaction known under conditions of normal use.

**Conditions to avoid**
Contact with incompatible materials.

**Incompatible materials**
None known.

**Hazardous decomposition products**
NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

**Information on likely routes of exposure**

- **Inhalation**: Knowledge about health hazard is incomplete.
- **Skin contact**: Knowledge about health hazard is incomplete.
- **Eye contact**: Knowledge about health hazard is incomplete.
- **Ingestion**: This material may cause: Methemoglobinemia.
- **Symptoms related to the physical, chemical, and toxicological characteristics**: Not available.

**Information on toxicological effects**

**Acute toxicity**

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ropivacaine Related Compound A (CAS 21436-98-6)</td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>2042 mg/kg</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**: Knowledge about health hazard is incomplete.

**Serious eye damage/eye irritation**: Knowledge about health hazard is incomplete.

**Respiratory or skin sensitization**

- **Respiratory sensitization**: Knowledge about health hazard is incomplete.
- **Skin sensitization**: Knowledge about health hazard is incomplete.
- **Germ cell mutagenicity**: Knowledge about mutagenicity is incomplete.

**Carcinogenicity**

- Suspected of causing cancer. The free base form of this material caused an increase in tumors in some animal studies.

- **IARC Monographs. Overall Evaluation of Carcinogenicity**
  - Not listed.

  - Not regulated.

- **US. National Toxicology Program (NTP) Report on Carcinogens**
  - Not listed.

**Reproductive toxicity**

Knowledge about health hazard is incomplete.

**Specific target organ toxicity - single exposure**

Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure**

Knowledge about health hazard is incomplete.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Further information**

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.
12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT Not regulated as dangerous goods.

IATA Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4) Not listed.

SARA 304 Emergency release notification Not regulated.


Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting) Not regulated.
Other federal regulations

- **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**
  - Not regulated.
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**
  - Not regulated.
- **Safe Drinking Water Act (SDWA)**
  - Not regulated.

US state regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**: This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

- **Issue date**: 07-08-2005
- **Revision date**: 10-23-2018
- **Version #**: 04

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