SAFETY DATA SHEET

1. Identification

Product identifier: Dexketoprofen Tromethamine

Other means of identification
- Catalog number: 1179118
- Chemical name: Benzenacetic acid, 3-benzoyl-α-methyl-, (+)-, with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)
- Synonym(s): (S)-(+)–Ketoprofen tromethamine * Dexketoprofen trometamol

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

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- 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
- Acute toxicity, oral: Category 3
- Skin corrosion/irritation: Category 2
- Serious eye damage/eye irritation: Category 2B
- Sensitization, skin: Category 1
- Reproductive toxicity: Category 2
- Specific target organ toxicity, repeated exposure: Category 1 (gastrointestinal tract, cardiovascular system)

OSHA hazard(s): Not classified.

Label elements

Signal word: Danger

Hazard statement: Toxic if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (gastrointestinal tract, cardiovascular system) through prolonged or repeated exposure.

Precautionary statement

Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

Response: If on skin: Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Rinse mouth. If exposed or concerned: Get medical advice/attention.

Storage: Store locked up.

Disposal: Dispose of contents/container to an approved disposal site.
Hazard(s) not otherwise classified (HNOC)  
Not classified.

3. Composition/information on ingredients

Substance

<table>
<thead>
<tr>
<th>Hazardous components</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Dexketoprofen Tromethamine</td>
<td>(S)-(+-)Ketoprofen tromethamine</td>
<td>156604-79-4</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Dexketoprofen trometamol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation  
Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact  
Wash off with soap and plenty of water. Remove contaminated clothing. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact  
Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.

Ingestion  
Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms/effects, acute and delayed  
Irritation of eyes and mucous membranes. May cause allergic skin reaction.

Indication of immediate medical attention and special treatment needed  
Treatment of nonsteroidal anti-inflammatory drug (NSAID) overdose should be symptomatic and supportive and may include the following: Induce vomiting (DO NOT use syrup of ipecac) or perform gastric lavage. Administer activated charcoal as a slurry. For gastrointestinal hemorrhage, monitor stool guaiac and administer antacids or sucralfate. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reactions, administer oxygen, antihistamines, epinephrine, or corticosteroids. Nephritis or nephrotic syndrome, thrombocytopenia, or hemolytic anemia may respond to glucocorticoid administration. For severe acidosis, administer sodium bicarbonate. Administer as required: plasma volume expanders for severe hypotension; diazepam or other benzodiazepine for convulsions; vitamin K1 for hypoprothrombinemia; and/or dopamine plus dobutamine intravenously to prevent or reverse early indications of renal failure. Forced diuresis, alkalization or urine, and hemoperfusion may not be useful. (Poisindex) (USP DI)

General information  
Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

5. Fire-fighting measures

Suitable extinguishing media  
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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  
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods  
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

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

Methods and materials for containment and cleaning up  
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.
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.

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

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact.

Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

220.6 - 221.2 °F (104.8 - 105.1 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

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

Not available.

Vapor density

Not available.

Relative density

Not available.
Solubility in water: Very soluble.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Other information:
Molecular formula: C16H14O3 . C4H11NO3
Molecular weight: 375.42
Solubility (other): Very soluble in methanol and in dimethyl sulfoxide; fairly soluble in ethanol; slightly soluble in isopropyl alcohol; and practically insoluble in chloroform, in ethyl ether, and in hexane.

10. Stability and reactivity
Reactivity: No reactivity hazards known.
Chemical stability: Material is stable under normal conditions.
Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
Conditions to avoid: None known.
Incompatible materials: None known.
Hazardous decomposition products: NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure:
Ingestion: Toxic if swallowed.
Inhalation: Due to lack of data the classification is not possible.
Skin contact: May cause an allergic skin reaction. Causes skin irritation.
Eye contact: Causes eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics:
Delayed and immediate effects of exposure:
Cross sensitivity: Persons sensitive to one nonsteroidal anti-inflammatory drug (NSAID), including aspirin, may be sensitive to this material also.
Medical conditions aggravated by exposure:
Acute toxicity: Toxic if swallowed.
Skin corrosion/irritation: Causes skin irritation.
Serious eye damage/eye irritation: Causes eye irritation.
Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: May cause an allergic skin reaction. Allergic reactions have been reported in literature following the therapeutic use of a related material.
Germ cell mutagenicity: Due to lack of data the classification is not possible.
Carcinogenicity: Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. A related material has not caused cancer in animal studies.
Reproductive toxicity: Suspected of damaging fertility or the unborn child.
Therapeutic use of nonsteroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labor, delayed birth, and decreased pup survival rates. Studies in animals with a related material showed maternal and fetal toxicity, but no impairment of fertility or teratogenicity.
Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

Causes damage to organs (gastrointestinal tract, cardiovascular system) through prolonged or repeated exposure.

Aspiration hazard

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

12. Ecological information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

Local disposal regulations

Not available.

Hazardous waste code

Not regulated.

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

UN number: UN2811
UN proper shipping name: Toxic solid, organic, n.o.s. (Dexketoprofen Tromethamine)
Transport hazard class(es): 6.1
Subsidiary class(es): Not available.
Packing group: III

IATA

UN number: UN2811
UN proper shipping name: Toxic solid, organic, n.o.s. (Dexketoprofen Tromethamine)
Transport hazard class(es): 6.1
Subsidiary class(es): Not available.
Packing group: III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.

15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No
### 16. Other information, including date of preparation or last revision

**Issue date** | 09-06-2013
---|---
**Version #** | 01
**Further information** | Not available.

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