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

Hazardous components

Chemical name | Common name and synonyms | CAS number | %
--- | --- | --- | ---
Dexketoprofen Tromethamine | (S)-(+)-Ketoprofen tromethamine | 156604-79-4 | 100

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)

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)
-
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
SARA 302 Extremely hazardous substance No
SARA 311/312 Hazardous chemical No

Other federal regulations
Safe Drinking Water Act (SDWA) Not regulated.
Food and Drug Administration (FDA) 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>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<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)

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

Issue date          09-06-2013
Version #            01
Further information  Not available.
Disclaimer           USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.