1. Identification

Product identifier: Etoricoxib

Other means of identification
- Catalog number: 1268863
- Chemical name: 2,3’-Bipyridine, 5-chloro-6’-methyl-3-[4-(methylsulfonyl)phenyl]-

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 4

OSHA hazard(s): Not classified.

Label elements

Signal word: Warning

Hazard statement: Harmful if swallowed.

Precautionary statement
- Prevention: Do not eat, drink or smoke when using this product.
- Response: Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell.
- Storage: Not available.
- Disposal: Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Substance: Etoricoxib

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etoricoxib</td>
<td></td>
<td>202409-33-4</td>
<td>100</td>
</tr>
</tbody>
</table>

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 thoroughly. If ingestion of a large amount does occur, call a 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.

Most important symptoms/effects, acute and delayed

Not available.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Administer activated charcoal with sorbitol to decrease absorption. Monitor serum electrolytes, renal function, and urinalysis. Support respiratory and cardiovascular function. Manage gastrointestinal hemorrhage with standard treatment measures. This material is not dialyzable.

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 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. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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.

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 powered 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 to off-white powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

260.6 - 262.4 °F (127 - 128 °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

Practically insoluble.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Molecular formula

C18H15ClN2O2S

Molecular weight

358.84

Solubility (other)

Freely soluble in methanol, in tetrahydrofuran, in dimethylsulfoxide, in methyl ethyl ketone, in dimethylformamide, and in chloroform; soluble in isopropyl acetate, in ethanol, and in toluene; sparingly soluble in isopropanol.

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. SOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion

Harmful if swallowed.
Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Cross sensitivity
Persons sensitive to salicylates or to other nonsteroidal anti-inflammatory agents may be sensitive to this material also.

Medical conditions aggravated by exposure

Acute toxicity
Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etoricoxib (CAS 202409-33-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>1499 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irritancy test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Non-irritant.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organ: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Duration: 7 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Due to lack of data the classification is not possible. Anaphylactic reactions following therapeutic use have been reported.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Due to lack of data the classification is not possible. There have been reports of anaphylactic reactions following therapeutic use of this material.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on available data, the classification criteria are not met. Negative in a battery of tests.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Hepatocellular and thyroid follicular cell adenomas observed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Duration: 2 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity studies Result: Negative.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on available data, the classification criteria are not met. The therapeutic use of nonsteroidal anti-inflammatory agents should be avoided during the second half of pregnancy because of possible adverse effects on the fetus (such as premature closure of the ductus arteriosus) and delayed labor.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 mg/kg/day Developmental studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: No developmental abnormalities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 mg/kg/day Developmental studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: No developmental abnormalities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 mg/kg/day Developmental studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Low incidence of cardiovascular malformations and post-implantation loss.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

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
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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>
</tbody>
</table>
Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Korea | Existing Chemicals List (ECL) | No
New Zealand | New Zealand Inventory | No
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

*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 | 10-19-2011
Revision date | 05-24-2013
Version # | 03
Further information | Not available.
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Revision Information
This document has undergone significant changes and should be reviewed in its entirety.