1. Identification

Product identifier: Eicosapentaenoic Acid Ethyl Ester

Other means of identification

- Catalog number: 1234307
- CAS number: 86227-47-6
- Synonyms: EPA ethyl ester * Ethyl icosapentate
- Chemical name: 5,8,11,14,17-Eicosapentaenoic acid, ethyl ester

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: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  United States
- 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: Not classified.

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

- Hazard symbol: None.
- Signal word: None.
- Hazard statement: Not available.
- Precautionary statement:
  - Prevention: Not available.
  - Response: Not available.
  - Storage: Not available.
  - Disposal: Not available.

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

Supplemental information: None.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eicosapentaenoic Acid Ethyl Ester</td>
<td>EPA ethyl ester Ethyl icosapentate</td>
<td>86227-47-6</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

- Inhalation: 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.
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

None known.

Provide general supportive measures and treat symptomatically.

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 fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
Do not use water jet as an extinguisher, as this will spread the fire.

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

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

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

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. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of vapors. 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
Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

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.

Cover all containers for solutions and slurries while being transferred.

Precautions for safe handling

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of vapors. 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

Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Avoid discharge into drains, water courses or onto the ground.

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).

Appropriate engineering controls
For laboratory operations, use good technique and limit open handling. 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.

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.

Other
Wear lab coat. 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.

Respiratory protection
Respirators are generally not required for laboratory operations. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

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.

9. Physical and chemical properties
Appearance
Appearance descriptions are general information and not specific to any USP lot.

Physical state
Liquid.

Form
Liquid.

Color
Clear.

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
> 320.0 °F (> 160.0 °C)

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(ies)

Solubility (water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Chemical family
Omega-3-acid ethyl ester.

Molecular formula
C22-H34-O2

Molecular weight
330.5

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
Alkalis.

Hazardous decomposition products
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
Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and toxicological characteristics
Information on toxicological effects

### Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eicosapentaenoic Acid Ethyl Ester (CAS 86227-47-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 20 g/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>&gt; 20 g/kg</td>
<td></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 sensitization hazard is incomplete.

- **Skin sensitization**
  Knowledge about sensitization hazard is incomplete.

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

#### Mutagenicity

- Ames test (Salmonella typhimurium), (with omega-3-acid ethyl esters)
  Result: Negative (+/- activation)
- Ames test (Salmonella typhimurium; E. coli), (with omega-3-acid ethyl esters)
  Result: Negative (+/- activation)
- In vivo (Mouse) micronucleus test, (with omega-3-acid ethyl esters)
  Result: Negative.
- Mutagenicity, Chromosomal aberration assay in CHO cells (with omega-3-acid ethyl esters)
  Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

- 2000 mg/kg/day Carcinogenicity, (oral doses of omega-3-acid ethyl esters)
  Result: Did not increase incidence of tumors.
  Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

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

#### Reproductivity

- < 1 g/kg Reproduction test
  Result: Negative: Did not increase the incidence of birth defects.
  Species: Rabbit
- < 3 g/kg Reproduction test
  Result: Negative: Did not adversely effect fertility and did not cause birth defects.
  Species: Rat

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

Knowledge about health hazard is incomplete.

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

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 established.

**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 not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

**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.

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**
- Immediate Hazard - No
- Delayed Hazard - No
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**
Not listed.

**SARA 311/312 Hazardous chemical**
No

**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**
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>
</tbody>
</table>
Country(s) or region | Inventory name                                                                 | On inventory (yes/no) |
---------------------|-------------------------------------------------------------------------------|-----------------------|
Canada              | Domestic Substances List (DSL)                                                | No                    |
Canada              | Non-Domestic Substances List (NDSL)                                           | No                    |
China               | Inventory of Existing Chemical Substances in China (IECSC)                    | No                    |
Europe              | European Inventory of Existing Commercial Chemical Substances (EINECS)        | No                    |
Europe              | European List of Notified Chemical Substances (ELINCS)                        | No                    |
Japan               | Inventory of Existing and New Chemical Substances (ENCS)                      | 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)
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          | 12-19-2011
Revision date       | 03-09-2018
Version #           | 03
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