1. Identification

Product identifier: Atorvastatin Related Compound D

Other means of identification:
- Catalog number: 1044550
- CAS number: 148146-51-4
- Synonyms: Oxirane impurity
- Chemical name: 3-(4-fluorobenzoyl)-2-isobutyryl-3-phenyl-oxirane-2-carboxylic acid phenylamide

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
- United States
- Website: www.usp.org
- E-mail: RS TECH@usp.org
- Telephone: RS Technical Services 301-816-8129

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: Pharmaceutical related compound of unknown potency.

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>Atorvastatin Related Compound D</td>
<td>Oxirane impurity</td>
<td>148146-51-4</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. 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.

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

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

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

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. 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.

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).

Appropriate engineering controls
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**
Chose 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**
  Powder.
- **Color**
  Light yellow. Off-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**
  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**
  - **Molecular formula**
    C26H22FNO4
  - **Molecular weight**
    431.46

10. **Stability and reactivity**

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

Chemical stability

No dangerous reaction known under conditions of normal use.

Possibility of hazardous reactions

Contact with incompatible materials.

Conditions to avoid

None known.

Incompatible materials

NOx, F-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Hazardous decomposition products

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
Not available.

Information on toxicological effects

Acute toxicity
Not known.

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
Knowledge about carcinogenicity is incomplete.

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
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.
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 not known to be 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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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

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>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
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<tr>
<td>Country(s) or region</td>
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<tr>
<td>---------------------------</td>
<td>-------------------------------------------------------------------------------</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</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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<td>New Zealand</td>
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<td>Philippines</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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>05-01-2013</th>
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<tbody>
<tr>
<td>Revision date</td>
<td>09-21-2018</td>
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<tr>
<td>Version #</td>
<td>02</td>
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