1. Identification

Product identifier: Irbesartan Related Compound A

Other means of identification:
- Catalog number: 1347711
- Chemical name: 1-pentanoylamino-cyclopentanecarboxylic acid [2'-(1H-tetrazol-5-yl)-biphenyl-4-ylmethyl]-amide

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

Note: Information on the chemical, physical, and toxicological properties of this material is not readily available. Individuals working with this chemical should consider it to be potentially hazardous even if its actual hazards may be uncharacterized or unknown.

Physical hazards: Not classified.

Health hazards: Not classified.

OSHA hazard(s): Not classified.

Label elements:
- Hazard symbol: No symbol.
- Signal word: Not available.
- Hazard statement: Not available.

Precautionary statement:
- Prevention: Not available.
- Response: Not available.
- Storage: Not available.
- Disposal: Not available.

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

3. Composition/information on ingredients

Substance: Irbesartan Related Compound A

Non-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>Irbesartan Related Compound A</td>
<td>748812-53-5</td>
<td>100</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: 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
Indication of immediate medical attention and special treatment needed
General information

Not available.
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
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

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

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. Clean surface thoroughly to remove residual contamination.

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
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.

Hand protection

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).

### General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>White powder.</td>
</tr>
<tr>
<td>Physical state</td>
<td>Solid.</td>
</tr>
<tr>
<td>Form</td>
<td>Powder.</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td></td>
</tr>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Not available.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Other information</td>
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</tr>
<tr>
<td>Chemical family</td>
<td>Tetrazole.</td>
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<tr>
<td>Molecular formula</td>
<td>C25H30N6O2</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>446.54</td>
</tr>
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</table>

### 10. Stability and reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No reactivity hazards known.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Material is stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>No dangerous reaction known under conditions of normal use.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>None known.</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.</td>
</tr>
</tbody>
</table>

### 11. Toxicological information

<table>
<thead>
<tr>
<th>Information on likely routes of exposure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
</tbody>
</table>
Symptoms related to the physical, chemical, and toxicological characteristics
Not available.

Acute toxicity
Due to lack of data the classification is not possible.

Skin corrosion/irritation
Due to lack of data the classification is not possible.

Serious eye damage/eye irritation
Due to lack of data the classification is not possible.

Respiratory sensitization
Due to lack of data the classification is not possible.

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

Germ cell mutagenicity
Due to lack of data the classification is not possible.

Carcinogenicity
Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Reproductive toxicity
Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure
Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

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
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
Not available.

Hazardous waste code
Not available.

Waste from residues / unused products
Dispose of in accordance with local regulations. 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 - No
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:
- 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: 01-25-2011
- Revision date: 05-08-2015
- Version #: 02
- Further information: Not available.
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Revision Information: This document has undergone significant changes and should be reviewed in its entirety.