

SAFETY DATA SHEET

Reviewed: 09-Apr-2024

Expiry extended to: 09-Apr-2027

1. Identification

| | | |
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| Product identifier | Indinavir | |
| Other means of identification | | |
| Catalog number | 1339178 | |
| Chemical name | D-erythro-Pentonamide, 2,3,5-trideoxy-N-(2,3-dihydro-2-hydroxy-1H-inden-1-yl)-5-[2-[[[(1,1-dimethylethyl)amino]carbonyl]-4-(3-pyridinylmethyl)-1-piperazinyl]-2(phenylmethyl)-, monohydrate, [1(1S,2R),5(S)]- | |
| 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 | Skin corrosion/irritation | Category 2 |
| OSHA hazard(s) | Not classified. | |
| Label elements | | |



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| Signal word | Warning | |
| Hazard statement | Causes skin irritation. | |
| Precautionary statement | | |
| Prevention | Wash thoroughly after handling. Wear protective gloves. | |
| Response | If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. | |
| Storage | Not available. | |
| Disposal | Not available. | |
| Hazard(s) not otherwise classified (HNOC) | Not classified. | |

3. Composition/information on ingredients

Substance

Hazardous components

| Chemical name | Common name and synonyms | CAS number | % |
|---------------|--------------------------|-------------|-----|
| Indinavir | | 180683-37-8 | 100 |

4. First-aid measures

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| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. |
| Skin contact | Remove contaminated clothing. Wash off with soap and plenty of water. If skin irritation occurs: Get medical advice/attention. |

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| Eye contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. |
| Most important symptoms/effects, acute and delayed | Irritant effects. |
| Indication of immediate medical attention and special treatment needed | Treatment of antiviral protease inhibitor overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Consider gastric lavage if it can be performed soon after ingestion, unless contraindicated. Protect airway and control seizures first. For seizures, administer a benzodiazepine intravenously. Consider phenobarbital or propofol if seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, need for endotracheal intubation, hypoglycemia, electrolyte disturbances, and hypoxia. (Meditext) |
| 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

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| Suitable extinguishing media | Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ . |
| 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. |
| Specific methods | Use standard firefighting procedures and consider the hazards of other involved materials. |

6. Accidental release measures

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| 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

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| 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

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| 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 powdered latex gloves should be avoided due to the risk of latex allergy. |

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| 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

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| Appearance | White crystalline powder. |
| Physical state | Solid. |
| Form | Powder. |
| Odor | Not available. |
| Odor threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | 316.4 °F (158 °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) | 2.66 |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Molecular formula | C36H47N5O4 · H2O |
| Molecular weight | 631.81 |
| Solubility (other) | Freely soluble in ethanol and in chloroform; soluble in acetone. |

10. Stability and reactivity

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| Reactivity | No reactivity hazards known. |
| Chemical stability | Stable at 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

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| Ingestion | Based on available data, the classification criteria are not met. |
| Inhalation | Due to lack of data the classification is not possible. |

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| Skin contact | Causes skin irritation. | |
| Eye contact | Based on available data, the classification criteria are not met. | |
| Symptoms related to the physical, chemical, and toxicological characteristics | Blood in urine. Lower back or side pain. Yellow eyes and/or skin. Antiviral protease inhibitors: Nausea. Diarrhea. Vomiting. Constipation. Headache. Sweating. Fainting. Weakness. Dizziness. Drowsiness. Abdominal pain. Mouth ulcers. Dry lips, mouth, and skin. Change in the sense of taste. Sore throat. Throat irritation. Lack of muscle coordination. Shortness of breath. Loss of appetite. Trouble sleeping. Tingling and numbness. | |
| Delayed and immediate effects of exposure | Kidney stones. | |
| Medical conditions aggravated by exposure | Kidney stones. Antiviral protease inhibitors: Bleeding disorders. Impaired liver function. Diabetes. | |
| Acute toxicity | Based on available data, the classification criteria are not met. | |
| Product | Species | Test Results |
| Indinavir (CAS 180683-37-8) | | |
| <i>Oral</i> | | |
| LD50 | Mouse | > 5000 mg/kg |
| | Rat | > 5000 mg/kg |
| Skin corrosion/irritation | Causes skin irritation. | |
| Serious eye damage/eye irritation | Based on available data, the classification criteria are not met. | |
| Local effects | | |
| Irritancy test | | |
| Result: Irritant. | | |
| Species: Rabbit | | |
| Organ: Eye | | |
| Severity: Minimal. | | |
| irritancy test | | |
| Result: Irritant. | | |
| Species: Rabbit | | |
| Organ: Skin | | |
| Severity: Moderate. | | |
| 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. Data from germ cell mutagenicity tests were not found. | |
| Mutagenicity | | |
| Alkaline elution assay | | |
| Result: Negative. | | |
| Ames assay | | |
| Result: Negative. | | |
| Chromosome aberration assay | | |
| Result: Negative. | | |
| DNA breakage and mammalian cell mutagenesis assays | | |
| Result: Negative. | | |
| In vivo chromosome aberration study | | |
| Result: Negative. | | |
| Carcinogenicity | Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. | |
| 640 mg/kg Carcinogenicity study | | |
| Result: In males, an increased incidence of thyroid tumors occurred. In females, there was no increased incidence of tumors. | | |
| Species: Rat | | |
| 70 mg/kg/day Carcinogenicity study | | |
| Result: No increased incidence of any tumor type. | | |
| Species: Mouse | | |
| Reproductive toxicity | Based on available data, the classification criteria are not met. | |
| Reproductivity | | |
| 160 mg/kg/day Reproductivity study | | |
| Result: An increased incidence of supernumerary and cervical ribs occurred. | | |
| Species: Rat | | |
| 240 mg/kg/day Reproductivity study | | |
| Result: No increased incidence of birth defects. | | |
| Species: Rabbit | | |

Reproductivity

640 mg/kg/day Reproductivity study
Result: No increased incidence of birth defects.
Species: Rat
80 mg/kg/day Reproductivity study
Result: No increased incidence of birth defects.
Species: Dog

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

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 - 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

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | 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)

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

Issue date 05-22-2009

Revision date 05-05-2014

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.