

1. Identification

Product identifier	Indinavir System Suitability	
Other means of identification		
Catalog number	1339189	
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		



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. Take off contaminated clothing and wash before reuse.	
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 System Suitability		180683-37-8	100

4. First-aid measures

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.
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

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

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.
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.
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 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

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

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	Due to lack of data the classification is not possible.
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 System Suitability (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		
640 mg/kg/day Reproductivity study		
Result: No increased incidence of birth defects.		
Species: Rat		

Reproductivity

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	04-21-2015
Version #	02
Further information	Not available.
Disclaimer	Not available.
Revision Information	This document has undergone significant changes and should be reviewed in its entirety.