




SAFETY DATA SHEET

1. Identification

Product identifier	Abacavir Sulfate Racemic	
Other means of identification		
Catalog number	1000419	
Chemical name	4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (2:1)	
Recommended use	For analytical laboratory 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	
Telephone	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	Serious eye damage/eye irritation	Category 1
	Sensitization, skin	Category 1
	Germ cell mutagenicity	Category 2
	Carcinogenicity	Category 1
	Reproductive toxicity	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		

Signal word	Danger
Hazard statement	May cause an allergic skin reaction. Causes serious eye damage. Suspected of causing genetic defects. May cause cancer. Suspected of damaging fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be allowed out of the workplace.
Response	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Abacavir Sulfate		188062-50-2	50
Abacavir Sulfate Enantiomer		935777-88-1	50

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

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	Wash off immediately with soap and plenty of water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Get medical attention if irritation develops and persists.
Eye contact	Get medical attention if irritation develops and persists. Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Continue rinsing. Get medical attention immediately.
Ingestion	Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Hypersensitivity reactions. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of antiviral nucleoside overdose may include the following: Administer activated charcoal as a slurry. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For severe metabolic acidosis, correct with intravenous sodium bicarbonate. Riboflavin (oral or intravenous) and L-carnitine have also been used to treat patients with severe lactic acidosis associated with nucleoside analogs.
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	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
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.
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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Methods and materials for containment and cleaning up

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. For waste disposal, see section 13 of the SDS.

Environmental precautions

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

7. Handling and storage

Precautions for safe handling

Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. 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. Use of a designated area is recommended for handling of potent materials. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Components

Industrial Use Components	Type	Value
Abacavir Sulfate (CAS 188062-50-2)	TWA	600 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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

Train employees in proper gowning and degowning practices. 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. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose 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 USP materials.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form	Powder.
Color	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	
Chemical family	Synthetic carbocyclic nucleoside analogue.
Molecular formula	(C ₁₄ H ₁₈ N ₆ O) ₂ . H ₂ SO ₄
Molecular weight	670.74

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	Strong oxidizing agents.
Hazardous decomposition products	NO _x . SO _x . 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	May cause an allergic skin reaction.
Eye contact	Causes serious eye damage.
Ingestion	This material may cause: Hypersensitivity reactions.

Symptoms related to the physical, chemical and toxicological characteristics Rash. Fever. Gastrointestinal disturbances. Fatigue. Headache. Cough. Difficulty breathing. Eye pain. Eye redness. Lactic acidosis. Liver damage.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Abacavir Sulfate (CAS 188062-50-2)		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Causes serious eye damage.	
Local effects		
Abacavir Sulfate		Draize test Result: Negative Species: Rabbit Organ: Skin Eye irritation Result: Positive Species: Rabbit Severity: Severe
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	May cause an allergic skin reaction. Hypersensitivity reactions involving multiple organs and progressive symptoms have been reported in 3 - 5% of the population receiving therapeutic abacavir.	
Abacavir Sulfate		Maximisation Test Result: Negative Species: Guinea pig Organ: Skin.
Germ cell mutagenicity	Suspected of causing genetic defects.	
Mutagenicity		
Abacavir Sulfate		1000 mg/kg Micronucleus assay, Positive in males. Result: Positive Chromosomal aberration, In vitro human lymphocytes Result: Positive Mutagenicity, Mouse lymphoma cell mutation assay, GLP assay Result: Positive
Carcinogenicity	May cause cancer.	
Abacavir Sulfate		110 mg/kg/day Carcinogenicity, Long-term dietary study; increased incidence of malignant tumors of the clitoral gland and liver of females and the preputial gland of males were observed. Species: Mouse 600 mg/kg/day Carcinogenicity, Increased incidence of malignant tumors of the clitoral gland and liver of females, and the preputial gland of males; increased incidence of nonmalignant thyroid and hepatic tumors in females. Species: Rat Carcinogenicity, Bioassay Result: Positive Species: Mouse Test Duration: 2 years
IARC Monographs. Overall Evaluation of Carcinogenicity	Not listed.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	Not listed.	
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.	
Reproductive toxicity	Suspected of damaging fertility or the unborn child.	

Reproductivity
Abacavir Sulfate

160 mg/kg/day Developmental, Embryo-fetal developmental study (oral)
Result: NOAEL
Species: Rat
500 mg/kg/day Developmental, Evidence of maternal adverse effects; decreased fetal weight and length, increased incidence of skeletal effects and fetal edema.
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 Based on available data, the classification criteria are not met.
Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

Components	Species	Test Results	
Abacavir Sulfate (CAS 188062-50-2)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	139 mg/l, 48 hours (static)
Fish	EC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss)	> 120 mg/l, 96 hours (static)

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

Abacavir Sulfate 1.08, = Log Kow

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.

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 a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Serious eye damage or eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity
Carcinogenicity
Reproductive toxicity

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 Proposition 65**

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. For more information go to www.P65Warnings.ca.gov.

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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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 12-08-2009

Revision date 09-23-2021

Version #

05

Further information

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer

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