

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Abacavir Tablets USP**

Recommended use : Pharmaceutical industry: Dosage form.
Therapeutic category: Antiviral

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

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Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Magnesium stearate	557-04-0	1 - 5

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not available.

Synonyms : Not available.

Chemical family : Synthetic carbocyclic nucleoside analogue

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : Flush with copious amounts of water. Seek medical attention if irritation persist.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

Section 5. Fire Fighting Measures

- Specific hazard arising from the chemical** : During fire, gases hazardous to health may be formed.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

- Methods and materials for containment and cleaning up** : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, refer to section 8 of the SDS.

Section 7. Handling and Storage

- Precautions for safe handling** : Avoid breathing dust.
- Conditions for safe storage** : Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)

Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, appropriate PPE may be required that includes NIOSH approved respirators.

EYE/FACE PROTECTION: Wear approved safety eyewear if eye contact is possible.

SKIN PROTECTION: Where there is a risk of contact when handling, wear suitable skin protection (e.g., gloves, lab coat/uniform) having resistance to the product.

HYGIENE MEASURES: In the event clothing becomes contaminated, remove promptly. Launder before use. When handling, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : Tablets.

pH : Not available.

Odor : Not available.

Melting point/Freezing point : Not available.

Odor threshold : Not available.

Boiling point : Not available.

Conditions of instability : No additional remark.

Volatility : Not available.

Decomposition temperature : Not available.

Specific gravity : Not available.

Partition Coefficient: : Not available.

Evaporation rate : Not available.

Viscosity : Not available.

Vapor density : Not available.

Flash points : Not available.

Relative density : Not available.

Flammable limits : Not available.

Vapor pressure : Not available.

Autoignition temperature : Not available.

Flammability : Emits toxic fumes under fire conditions.

Solubility : Not available.

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable.

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : When heated to decomposition material emits toxic fumes.

Incompatible materials/ Conditions to avoid : Not available.

Section 11. Toxicological Information

Information on the likely routes of exposure : As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances.

Toxicity data : Abacavir sulfate:
LD50: > 2000 mg/kg (oral-rat)
LD50: > 2000 mg/kg (dermal-rabbit)

Skin contact: May cause an allergic skin reaction.
Eye contact: Causes serious eye irritation.

Delayed and immediate effects and also chronic effects from short and long term exposure : Possible hypersensitization.
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. Neoplasms occurred in the preputial gland in male mice and rats and in the clitoral gland of female mice and rats, neoplasms occurred in the liver of female rats, and benign tumors occurred in the liver and thyroid of female rats during two-year carcinogenicity studies in mice and rats receiving abacavir orally at doses up to 330 mg/kg/day and 600 mg/kg/day, respectively.

Reproductive and Developmental Effects: Pregnancy Category: C. Depressed fetal body weight, reduced crown-rump length, and increased incidences of fetal anasarca and skeletal malformations were observed in rats given abacavir at a dose of 1000 mg/kg during pregnancy. Doses of 500 mg/kg/day in rats were associated with increased resorptions and decreased body weights. In female rats, 500 mg/kg increased the incidence of stillbirths. There was no evidence of drug-related developmental toxicity or increased fetal malformations in rabbits administered doses up to 700 mg/kg. No adverse effects on mating performance or fertility occurred in male or female mice administered abacavir at doses up to 500 mg/kg/day.

Mutagenicity: Abacavir was found to induce chromosomal aberrations, with and without activation, in an in vitro cytogenetic study in human lymphocytes. It was mutagenic in an L5178Y mouse lymphoma assay without, but not with, activation. Abacavir was clastogenic in an in vivo mouse bone marrow micronucleus assay in males, but not females. It was not found to be mutagenic in bacterial mutagenicity assays, with or without activation.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material, moderately or severely impaired liver function, and risk factors for liver disease such as obesity or prolonged nucleotide exposure.

Symptoms related to the physical, chemical and toxicological characteristics : Adverse effects may include body aches or pains; cough; diarrhea; difficulty breathing; fever; headache; nausea; numbness or tingling in face, hands, or feet; red or sore eyes; skin rash; sore throat; sores in the mouth; swelling of feet or lower legs; vomiting; unusual tiredness; loss of appetite; and trouble sleeping. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label	Additional information (e.g., special precautions, environmental hazards, transport in bulk)
TDG- road Canada/U.S.			Not regulated.			
ICAO-Air			Not regulated.			
ADR			Not regulated.			
IMDG Class			Not regulated.			

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS
Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
PDR Electronic Library
Apotex Product Monograph
U. S. Pharmacopeia

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Notice to Reader

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