

Safety data Sheet	
Company Name:	Strides Shasun Ltd SDS Number : SDS/D1-002-00
Section 1: Identification	
Product Identifier	Off white colored, capsule shaped, film coated tablets imprinted with "600" on one side and plain on other side.
Product name:	Efavirenz Tablets USP [600mg] [FC]
Trade name:	Not applicable
Product Code No.:	2003166
Relevant identified use of the substance or mixture and use advised against	
Recommended Use:	This material is a finished drug product for patient use. It is used to treat human immunodeficiency virus infection (HIV, AIDS).
Restrictions on Use:	Do not take internally unless instructed by a physician.
Details of the supplier of the safety data sheet:	
Manufacturer name:	Strides Shasun Limited
Address:	Strides Shasun Limited No 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bengaluru, Karnataka, India. 562106
Telephone Number-General:	91 8067 840307/309
Emergency Telephone Number:	91 8067 840307/309
<i>Note: This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).</i>	
Section 2: Hazard Identification:	
Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act	
Hazard Classification	Not applicable
Label Elements	Not applicable
Other Hazards	Not applicable
Unknown acute toxicity	No information available
Section 3: Composition/Information on Ingredients	
This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act	
Section 4: First aid measures	

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.	
General advice:	Never give anything by mouth to an unconscious person, IF exposed or concerned: Get medical advice/attention, Show this safety data sheet to the doctor in attendance
Inhalation:	Remove to fresh air.
Skin contact:	Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion:	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an Unconscious person. Call a physician.
Self-protection of the first aider:	First aider: Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Most important symptoms and effects both acute and delayed:	
Symptoms:	Nausea, Headache, Dizziness and Vomiting.
Indication of immediate medical attention and special treatment needed	
Treat symptomatically.	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Section 5: Fire Fighting Measures	
Extinguishing media	
Flammable Properties	Not available
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards arising from the chemical:	
Fire hazard:	Not flammable.
Explosive hazard:	Not an explosive.
Reactivity:	Hazardous reactions will not occur under normal conditions.
Hazardous combustion products:	Nitrogen oxides. Hydrogen halides.
Other information	Decontaminate protective clothing and equipment before reuse. Heating can release hazardous gases.
Advice for firefighters	
Precautionary measures in case of fire:	Standard procedure for chemical fires.
Firefighting instructions:	Use water spray or fog; do not use straight streams.
Protection of Firefighters:	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear
Other Information:	Refer to Section 9 for flammability properties.

Section 6: Accidental Release Measures	
This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.
For non-emergency personnel	
Personal Protective Equipment:	Use personal protective equipment as required.
For emergency responders	
Personal Protective Equipment:	Use personal protective equipment as required.
Emergency procedures:	Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.
Other Information:	Refer to protective measures listed in Sections 7 and 8.
Environmental precautions	
Environmental precautions	Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.
Methods and material for containment and cleaning up	
Methods for containment:	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up:	Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.
Prevention of secondary hazards:	Clean contaminated objects and areas thoroughly observing environmental regulations.
Reference to other sections	See section 8 for more information. See section 13 for more information.
Section 7: Handling and Storage	
Precautions for safe handling	
Patients/Consumers:	Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Advice on safe handling:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation.
Conditions for safe storage, including any incompatibilities	
Storage Conditions:	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.
Specific end use(s):	Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

Section 8: Exposure Controls and personal protection	
This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.	
Control Parameters:	
Exposure Limits	No information available
Exposure Controls	
Engineering Controls	Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Individual protection measures, such as personal protective equipment	
Hand protection:	Wear suitable gloves.
Eye/face protection:	If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.
Skin and body protection:	Wear suitable protective clothing.
Respiratory protection:	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.
General hygiene considerations:	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing.
Section 9: Physical and Chemical properties	
Information on physical and chemical Properties	
Material Description:	
Physical State:	Solid
Appearance:	Tablet
Color:	Off white
Odour:	No data available
Odour threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available

Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
Other Information	
VOC Content (%):	No data available
Section 10: Stability and Reactivity	
Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Extremes of temperature and direct sunlight.
Incompatible materials	Strong oxidizing agents, strong acids, and strong bases
Hazardous decomposition products	Decomposition will not occur under normal conditions
Section 11: Toxicological information	
Information on toxicological effects	
Information on likely routes of exposure	
Inhalation:	Specific test data for the substance or mixture is not available.
Ingestion:	Specific test data for the substance or mixture is not available.
Eye contact:	Specific test data for the substance or mixture is not available.
Skin contact:	Specific test data for the substance or mixture is not available.
Symptoms related to the physical, chemical and toxicological characteristics	
Symptoms:	Nausea, Headache, Dizziness and Vomiting.
Delayed and immediate effects as well as chronic effects from short and long-term exposure	
Skin corrosion/irritation:	May cause skin irritation.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Contains a known or suspected reproductive toxin. May cause harm to breastfed babies.
STOT - single exposure:	Based on available data, the classification criteria are not met.
STOT - repeated exposure:	Causes damage to organs through prolonged or repeated exposure. Classification based on data available for ingredients

Target organ effects:	Central nervous system, Skin and liver.
Aspiration hazard:	Based on available data, the classification criteria are not met.
Numerical measures of toxicity	
Acute toxicity	No information available.
Section 12: Ecological Information	
Ecotoxicity	No information available.
Persistence and degradability	No information available
Bioaccumulation	There is no data for this product.
Mobility	No information available.
Other adverse effects	No information available.
Section 13: Disposal Considerations	
Waste treatment methods	Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.
Section 14: Transport information	
Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.	
In accordance with DOT / ICAO / IATA / TDG	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class(es) Hazard Class:	Not regulated
Packing group	Not regulated
Environmental hazards	No
Special precautions for user	No information available
Transport in bulk according to Annex II of MARPOL and the IBC Code	Not applicable
Section 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	
International Regulations	
Ozone-depleting substances (ODS):	Not applicable
Persistent Organic Pollutants:	Not applicable
The Rotterdam Convention:	Not applicable
US Federal Regulations	

SARA 313:	Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.
CWA (Clean Water Act)	
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).	
CERCLA	
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.	
US State Regulations	
California Proposition 65:	This product does not contain any Proposition 65 chemicals.
U.S. State Right-to-Know Regulations	
US State Regulations:	This product does not contain any substances regulated by state right-to-know regulations
Canada	
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.	
Section 16: Other information	
Data Sources:	This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard CFR 1912.1200.
Other Information:	This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.
Reason for revision: (Include Change control number)	New Safety data sheet prepared
Revision date :	27/03/2018
Version Number:	00

CERTIFICATE FOR SAFETY DATA SHEET
Name of the product: Efavirenz Tablets USP {600mg} [FC]

Product Code: 2003166

SDS Number: SDS/D1-002-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	SHANKAR M.S	M.S. Shankar 27/03/18
Reviewed By (FD)	FD	Punit Shah	Punit Shah 27/03/2018
Reviewed By (RA)	RA	T. Nareesh Kumar	T. Nareesh Kumar 27/03/18
Approved By (FD)	FD	Sudashan Nimbalkar	Sudashan Nimbalkar 27/03/18
Authorized By (TSGQA/DQA)	DQA	B.S. HARISH PRASAD	B.S. Harish Prasad 27/03/2018

RD/FD/009/F-02/RO