Section1: Chemical Product and Company Identification

Product Name: Abacavir and Lamivudine tablets 600 mg/300 mg

Synonyms: --

CAS No.: --

Chemical Formula: --

Molecular Weight: --

NFPA Rating:

Health: - ; Flammability: - ; Reactivity: - ; Specific Hazard: -

Contact Information:

Corporate Address :
Laurus Labs Limited,
2nd Floor, Serene Chambers, Road No # 7, Banjara Hills, Hyderabad – 500034
Ph: 040 – 3980 4333

Section 2: Hazards Identification

Not considered hazardous when handled under normal conditions with good housekeeping.

Section 3: Composition/ Information on Ingredients

CAS #	Chemical name	Percent
188062-50-2	Abacavir Sulfate	45.5-54.5
134678-17-4	Lamivudine	19.8-22.8
9004-34-6	Microcrystalline cellulose (Ceolus UF 711)	19.6 – 23.6
9063-38-1	Sodium starch glycolate (Primojel Type A)	3.5 – 5.5
557-04-0	Magnesium stearate (Ligamed-MF-2V)	0.90 - 1.5
None assigned	Opadry Orange YS - 1 - 13065 - A	1.5-4.0

Section 4: First Aid Measures

Eye Contact
Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

Skin Contact
Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Inhalation
Physical form suggests that risk of inhalation exposure is negligible.

Ingestion
Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semiconscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Section 5: Fire and Explosion Data

Fire and Explosion Hazards
Not expected for the product, although the packaging is combustible.

Extinguishing Media

Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

Special Firefighting Procedures

For single units (packages): No special requirements needed.

For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products

Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Personal Precautions

Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods

Collect and place it in a suitable, properly labelled container for recovery or disposal.

Section 7: Handling and Storage

Handling

Avoid breaking or crushing tablets. No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

Storage condition

Store at 20°C - 25°C (68°F – 77° F); excursions permitted to 15°C - 30°C (59° F - 86° F).

Section 8: Exposure Controls/ Personal Protection

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields.

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Body Protection

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

For nuisance exposures use respirator cartridges. Use respirators and components tested and approved under appropriate government standards

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Section 9: Physical and Chemical Properties

Appearance	
Physical state & Colour	: Orange colored, capsule shaped, film coated tablets, debossed with 'LT' on one side and plain on the other side.
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point	: No data available
Boiling point	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper/lower flammability or explosive limits	: No data available
Vapour pressure	: No data available
Vapour density	: No data available
Relative density	: No data available
Water solubility	: No data available
Partition coefficient: noctanol /water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

Other safety information
No data available

Section 10: Stability and Reactivity Data

Stability
Stable under recommended storage conditions.

Section 11: Toxicological Information

Acute toxicity
Lamivudine
LD50: >2000mg/kg (Oral Rat)
Abacavir
LD50: >2000mg/kg (Oral Rat)
Carcinogenicity
Abacavir was administered orally at 3 dosage levels to separate groups of mice and rats in 2-year carcinogenicity studies. Results showed an increase in the incidence of malignant and non-malignant tumors. Malignant tumors occurred in the preputial gland of males and the clitoral gland of females of both species, and in the liver of female rats.
In addition, non-malignant tumors also occurred in the liver and thyroid gland of female rats. These observations were made at systemic exposures in the range of 6 to 32 times the human exposure at the recommended dose of 600 mg.
Long-term carcinogenicity studies with lamivudine in mice and rats showed no evidence of carcinogenic potential at exposures up to 10 times (mice) and 58 times (rats) the human exposures at the recommended dose of 300 mg.

Mutagenicity

Abacavir induced chromosomal aberrations both in the presence and absence of metabolic activation in an in vitro cytogenetic study in human lymphocytes. Abacavir was mutagenic in the absence of metabolic activation, although it was not mutagenic in the presence of metabolic activation in an L5178Y mouse lymphoma assay. Abacavir was clastogenic in males and not clastogenic in females in an in vivo mouse bone marrow micronucleus assay. Abacavir was not mutagenic in bacterial mutagenicity assays in the presence and absence of metabolic activation.

Lamivudine was mutagenic in an L5178Y mouse lymphoma assay and clastogenic in a cytogenetic assay using cultured human lymphocytes. Lamivudine was not mutagenic in a microbial mutagenicity assay, in an in vitro cell transformation assay, in a rat micronucleus test, in a rat bone marrow cytogenetic assay, and in an assay for unscheduled DNA synthesis in rat liver.

Impairment of Fertility

Abacavir or lamivudine did not affect male or female fertility in rats at a dose associated with exposures approximately 8 or 130 times, respectively, higher than the exposures in humans at the doses of 600 mg and 300 mg (respectively).

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Follow all federal state and local environmental regulations.

Section 14: Transport Information

UN number

ADR/RID: - IMDG: - IATA: -

UN proper shipping name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

Packaging group

ADR/RID: - IMDG: - IATA: -

Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

Special precautions for user

No data available

Section 15: Other Regulatory Information

No data available.

Section 16: Other Information

Disclaimer:

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does

not represent any guarantee of the properties of the product.

Revision Log:

Revision No.	Reason for revision	Effective Date
0.0	First Issue	11/11/2019

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