SAFETY DATA SHEET
Lamivudine and Zidovudine Tablets USP, 150 mg/300 mg

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING.
Material: Lamivudine and Zidovudine Tablets USP, 150 mg/300 mg
Company Name: Strides Arcolab Ltd,
Opp to IIM,
Bilekahalli, Arekare main Road,
Bangalore-560076

2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS RN</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAMIVUDINE</td>
<td>134678-17-4</td>
<td>23%</td>
</tr>
<tr>
<td>ZIDOVUDINE</td>
<td>30516-87-1</td>
<td>46%</td>
</tr>
<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>31%</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Fire and Explosion: Expected to be non-combustible
Health: Caution - Pharmaceutical agent. Eye irritant. May produce mutagenic effects in human cells. Exposure might occur via eyes; skin; ingestion. Health effects information is based on hazards of components.

* Environment: No environmental hazards have been identified for this material.

4. FIRST-AID MEASURES

Ingestion: Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention
Inhalation: Physical form suggests that risk of inhalation exposure is negligible.
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.
Eye Contact: Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention

NOTES TO HEALTH PROFESSIONALS

Medical Treatment: Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

Medically Conditions Caused or Aggravated by Exposure: None for occupational exposure.

Antidotes: No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

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

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.

Decontamination Procedures
No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING
Avoid breaking or crushing tablets.

General Requirements
No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT
LAMIVUDINE

Occupational Hazard Category
2

Exposure Limit
Occupational Exposure Limit
REPRODUCTIVE HAZARD

INGREDIENT
ZIDOVUDINE

Occupational Hazard Category
2

Exposure Limit
Occupational
350 mcg/m3 (8 HR TWA)

ENGINEERING CONTROLS

Exposure Controls
An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.

Containment
Open handling may result in overexposure.

Ventilation
Local exhaust ventilation (LEV) should be used in conjunction with other control measures as a means of removing material incidentally released.
PERSONAL PROTECTIVE EQUIPMENT
Eye Protection
Wear approved safety glasses with side shields or cover goggles if eye contact is possible.

Other Equipment or Procedures
None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance
White.

Colour
Tablet.

Physical Form
Stable.

Stability
This product is expected to be stable.

Conditions to Avoid
None for normal handling of this product.

10. TOXICOLOGICAL INFORMATION
Oral Toxicity
Not expected to be toxic following ingestion.

Inhalation Toxicity
No studies have been conducted.

Skin Effects
Irritation is not expected following direct contact.

Eye Effects
Irritation might occur following direct contact with eyes.

Target Organ Effects
Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.

Sensitisation
Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity
Possible human mutagen.

Carcinogenicity
No components are listed as carcinogens by IARC, NTP or US OSHA. Positive results occurred in some studies that are not considered to be relevant to occupational exposure conditions. Not expected to produce cancer in humans under occupational exposure conditions based upon negative results in laboratory assays.

Reproductive Effects
Contains components which have been classified as: Possible risk of toxicity in developing human offspring. Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Pharmacological Effects
This preparation contains ingredient(s) with the following activity: a nucleoside inhibitor of viral reverse transcriptase

11. ECOLOGICAL INFORMATION
Summary
No information is available about the potential of this product to produce adverse environmental effects. This material contains two or more active pharmaceutical ingredients that have been tested, and no environmental effects have been identified. Consult the MSDS of each ingredient for specific information about potential environmental effects. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient which is the majority component is provided below.

ECOTOXICITY
Aquatic
This material is not toxic to activated sludge microorganisms. This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

* Activated Sludge
IC50: > 1000 mg/l, 3 Hours, Activated sludge
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* Microbial Growth Inhibition
This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.
Minimum Inhibition Concentration:
250 mg/l, Aspergillus flavus
> 1000 mg/l, Azotobacter chroococcum
> 1000 mg/l, Chaetomium globosum
> 1000 mg/l, Nostoc sp.
> 1000 mg/l, Pseudomonas fluorescens

Daphnid
This material contains an active pharmaceutical ingredient that is not toxic to daphnids.
EC50: > 100 mg/l, 48 Hours, Daphnia magna, Static test
Chronic LOEC: 40 mg/l, 21 Days, Daphnia magna, Static renewal test
Chronic NOEC: 16 mg/l, 21 Days, Daphnia magna, Static renewal test

MOBILITY
* Solubility
This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volutility
This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.
Henry's Law Constant 3.50E-15 atm m³/mol, Estimated at 25°C

* Adsorption
This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

* Partitioning
This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION
* Hydrolysis
This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.
Half-Life, Neutral: > 1 Years, Measured

* Photolysis
This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.
Half-Life, Aqueous: 9.04 Hours, Measured, pH 7 Buffer Solution
UV/Visible Spectrum: 266 nm

Biodegradation
This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.
Percent Degradation: 0.23 %, 28 days, Modified Sturm test, Activated sludge
Percent Degradation: 50 %, 3 days, Modified Zahn-Wellens, primary biodegradation, loss of parent, Activated sludge

Aerobic - Ready
Aerobic - Inherent
Percent Degradation: 50 %, 3 days, Modified Zahn-Wellens, primary biodegradation, loss of parent, Activated sludge

* BIOACCUMULATION
This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.
12. DISPOSAL CONSIDERATIONS
Disposal Recommendations
Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements
Observe all local and national regulations when disposing of this product.

13. TRANSPORT INFORMATION
The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling Transport Information
Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

14. REGULATORY INFORMATION
The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

* EU Classification and Labelling
Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations
TSCA Status Exempt

15. OTHER INFORMATION
REGULATORY INFORMATION
European Union Classification and Labelling Requirements

TOXICOLOGY INFORMATION
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.