SAFETY DATA SHEET

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING.

Company Name	Stride Shasun Ltd Opposite to IIMB, Bilekahalli Bangalore – 560076 India **For emergency or** **Product information, call 1 877 244 9825**
Product Identifier:	Acarbose Tablets
Synonym:	Not Applicable
Trade Names:	None identified
ANDA No.:	090912
Product Use::	**Management of type 2 diabetes mellitus / Anti diabetic**
Restrictions on Use:	Refer product information leaflet (PIL) for restrictions on use and contraindications.

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).*

SECTION 2. HAZARDS IDENTIFICATION

Dose and Administration	Dosage of acarbose must be individualized on the basis of both effectiveness and tolerance while not exceeding the maximum recommended dose of 100 mg t.i.d. acarbose should be taken three times daily at the start (with the first bite) of each main meal. Acarbose should be started at a low dose, with gradual dose escalation as described below, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycemic control of the patient.
Adverse Effects	Gastrointestinal symptoms are the most common reactions to Acarbose.
Over Dose Effect	Unlike sulfonylureas or insulin, an overdose of Acarbose will not result in hypoglycemia. An overdose may result in transient increases in flatulence, diarrhea, and abdominal discomfort which shortly subside. In cases of overdosage the patient should not be given drinks or meals containing carbohydrates (polysaccharides, oligosaccharides and disaccharides) for the next 4–6 hours.
Contraindications	Acarbose contraindicated in patients with known hypersensitivity to the drug. Acarbose is contraindicated in patients with diabetic ketoacidosis or cirrhosis. Acarbose is also contraindicated in patients with inflammatory bowel disease, colonic ulceration, partial

intestinal obstruction or in patients predisposed to intestinal obstruction. In addition, Acarbose is contraindicated in patients who have chronic intestinal diseases associated with marked disorders of digestion or absorption and in patients who have conditions that may deteriorate as a result of increased gas formation in the intestine.

Pregnancy Category B

SECTION 3- COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	Percentage composition (Tentative)
Principle Component :		
Acarbose	56180-94-0	25mg/50mg/100mg
Inactive Ingredients :		
Corn Starch	9005-25-8	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Colloidal Silicon Dioxide	7631-86-9	Proprietary

4. FIRST-AID MEASURES

Eye Exposure Any material that contacts the eye should be washed out immediately with water. If easy to do,remove contact lenses if worn. Get medical attention if symptoms persist.

Skin Exposure Wash with soap and water. Get medical attention if symptoms occur.

Ingestion Call a physician or poison control center immediately.

Inhalation Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.

5. FIRE-FIGHTING MEASURES

Flammability Lower: N/A Upper: N/A

Flash Point Not Applicable

Extinguishing Media Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

Special Fire Fighting Procedures Wear full protective clothing and self-contained breathing apparatus.

Unusual Fire/Explosion Hazards Not Applicable

Hazardous Combustion Products Carbon dioxide, carbon monoxide, oxides of nitrogen.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED	Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations.Incineration of the waste at an approved facility is recommended.

7. HANDLING AND STORAGE

Precautions Handling Significant Quantities of Product	Observe good industrial hygiene practices.
Storage	Store at 20°C to 25 °C (68^0 to 77^0 F).Protect from moisture. Keep contianer tightly closed.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits:	None
Engineering Controls	Not required when handling tablets or containers. Ventilation should be matched to conditions.
Respiratory Protection	Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection	Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves.
Recommended Facilities	Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form	Tablet.

Appearance	25 mg Tablets: white to off white colour circular, biconvex tablets with "P210" engraved on one side and "25" on other side. 50 mg Tablets: white to off white colour circular, biconvex tablets with "P211" engraved on one side and "50" on other side. 100 mg Tablets: white to off white colour circular, biconvex tablets with "P212" engraved on one side and "100" on other side.

10. STABILITY AND REACTIVITY

Stability	Stable
Incompatibility	None known
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen
Conditions to Avoid	Excessive heat, light, moisture
Hazardous Polymerization	Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Active Ingredient	LD50 Oral (rat): 24,000 mg/kg LD50 Oral (mouse): 24,000 mg/kg
Carcinogenicity	Not listed as a carcinogen by NTP, IARC Monographs or OSHA.

12. ECOLOGICAL INFORMATION

Bio accumulation	Bio accumulation is low
BCG	3.2**
Persistence & Degradability	47% ,28 Days
Mobility in soil	NAIF
Surface tension	114.5 dyne/cm*
BOD_5	NAIF
COD	NAIF
Eco toxicity Effects	Risk of direct eco toxicity is low.

Natural pollution sources	Product of actinoplanes
LD_{50}(Fish-96h)	EC_{50}>1000mg/L, unspecified fish NOEC>1000mg/L
EC_{50}(Daphnies-48h)	EC_0> 1g/L, EC_{50}>1000mg/L,Daphnia spp. NOEC>1000 mg/L
IC_{50} (Algae-72h)	NAIF
EC_{50} (Bacteria)	EC_{50}>10000mg/L MGI:MIC>1000mg/L *Data from chemspider; **estimated by PBT profiler

13. DISPOSAL CONSIDERATIONS

Waste Disposal Considerations:	Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.
At home:	Discard away from children's reach.

14. TRANSPORT INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.

DOT: Not regulated

TDG: Not regulated

IATA: Not regulated

IMDG: Not regulated

15. REGULATORY INFORMATION

DEA: Acarbose is not a controlled substance.

FDA: Acarbose is an approved prescription medication.

Inventory Status: This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

This material is not listed on the DSL Inventory but is exempt.

16. OTHER INFORMATION

Disclaimer - 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.

Reason for revision: New SDS introduced.

Revision date: N.A.