



MATERIAL SAFETY DATA SHEET

Acarbose Tablets 25 mg, 50 mg and 100 mg

STRIDES ARCOLAB LIMITED

Opp. IIM, Bilekahalli,
Bannerghatta Road.
Bangalore-76, India

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Acarbose Tablets

Chemical Name: O-4,6-dideoxy- 4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)-2-cyclohexen-1-yl]amino]- α -D-glucopyranosyl-(1 \rightarrow 4)-O- α -D-glucopyranosyl-(1 \rightarrow 4)-D-glucose .

Molecular formula: C₂₅H₄₃NO₁₈

Molecular weight: 645.6

Indications: Acarbose Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Synonyms: None

2. COMPOSITION/INFORMATION ON INGREDIENTS

ACTIVE INGREDIENT/ CAS NUMBER: Acarbose / 56180-94-0

3. HAZARDS IDENTIFICATION

Emergency Overview:

Physical State: Tablets

25 mg Tablets: white to off white, circular biconvex tablets with "P210" engraved on one side and "25" on other side.

50 mg Tablets: white to off white, circular biconvex tablets with “P211” engraved on one side and “50” on other side.

100 mg Tablets: white to off white, circular biconvex tablets with “P212” engraved on one side and “100” on other side.

Odor: No data available

Primary route(s) of Entry: Ingestion.

Potential Health Effects:

Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form.

Eye Contact: Not expected to be a hazard to the eye in final pharmaceutical form.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.

Ingestion: May be harmful if ingested. Ingestion may cause abdominal pain, diarrhea, gastrointestinal upset, and other systemic effects.

Effects of Overexposure: The potential for exposure is reduced in finished pharmaceutical form. The signs of overdosage may include transient increases in abdominal pain, diarrhea, and flatulence which shortly subside. An overdose of acarbose will not result in hypoglycemia.

Target Organs: Small intestine

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 AND EXPLOSION HAZARDS

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 INFORMATION

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. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions Handling Significant Quantities of Product: Observe good industrial hygiene practices.

Storage : Store at 20° to 25°C (68° to 77°F). Protect from moisture. Keep container tightly closed.

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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, circular biconvex tablets with “P210” engraved on one side and “25” on other side.

50 mg Tablets: white to off white, circular biconvex tablets with “P211” engraved on one side and “50” on other side.

100 mg Tablets: white to off white, circular biconvex tablets with “P212” engraved on one side and “100” on other side.

Odor: No applicable information found
Boiling Point: No applicable information found
Melting Point: No applicable information found
Specific Gravity: No applicable information found
Flashpoint: No applicable information found
Solubility: No applicable information found
Density: No applicable information found
Vapor Pressure: No applicable information found

10. STABILITY AND REACTIVITY DATA

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. ENVIRONMENTAL IMPACT INFORMATION

No information is currently available on the environmental impact of this product.

13. DISPOSAL INFORMATION:

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 DATA

ABBREVIATIONS:

N/A – not applicable