

1. Identification

Product identifier **Acarbose Tablets**

Other means of identification

Identification: 25 mg Tablet debossed with product identification "54 311" on one side, and plain on the other.
 50 mg Tablet debossed with product identification "54 734" on one side, and plain on the other.
 100 mg Tablet debossed with product identification "54 251" on one side, and plain on the other.

Recommended use Management of type 2 diabetes mellitus

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name Boehringer Ingelheim Roxane Inc.

Address 1809 Wilson Road
 Columbus, Ohio 43228

Telephone (614) 276-4000

Emergency phone number (614) 276-4000

2. Hazard(s) identification

Physical hazards Not classified.

Health Hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word Warning

Hazard statement This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Incineration of waste at a an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
D-Glucose, O-4,6-dideoxy-4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)-2-cyclohexen-1-yl]amino]-α-D-glucopyranosyl-(1->4)-O-α-D-glucopyranosyl-(1->4)-		56180-94-0	25-100 mg

Composition comments Refer to Physician's Desk Reference for common components present at <1%

4. First-aid measures

Inhalation If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	The common side effects are abdominal pain, diarrhea, and flatulence. These adverse events are generally mild to moderate and tend to diminish in frequency and intensity with time. Additional adverse events reported include edema, ileus/subileus, jaundice and/or hepatitis with associated liver damage. An overdose of acarbose will not result in hypoglycemia.
Indication of immediate medical attention and special treatment needed	There is no specific antidote for acarbose overdose. In case of overdose, patients should not be given drinks or meals containing carbohydrates (polysaccharides, oligosaccharides and disaccharides) for 4 to 6 hours. In managing overdosage, consider the possibility of multiple drug involvement. Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Protect from moisture. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Ventilation should be matched to conditions.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Not required when handling tablets. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	If prolonged or repeated contact is likely, suitable protective gloves are recommended.
Other	If prolonged or repeated contact is likely, suitable protective clothing is recommended.
Respiratory protection	Not required when handling tablets. Use a NIOSH approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	None.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Round, white, biconvex tablets

Physical state Solid.

Form Tablet.

Color White to off-white.

Odor None.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Molecular formula C₂₅H₄₃NO₁₈

Molecular weight 645.6

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.

Skin contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust or powder may irritate the skin.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	The common side effects are abdominal pain, diarrhea, and flatulence. These adverse events are generally mild to moderate and tend to diminish in frequency and intensity with time. Additional adverse events reported include edema, ileus/subileus, jaundice and/or hepatitis with associated liver damage. An overdose of acarbose will not result in hypoglycemia.
Information on toxicological effects	
Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Dust in the eyes will cause irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	This product is not expected to be mutagenic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects. Pregnancy Category B
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Further information	See package insert.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	None.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations 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.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations Drug Enforcement Administration (DEA): Arcabose is not a controlled substance.
Food and Drug Administration (FDA): Arcabose is an approved antihyperglycemic prescription medication.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Not listed.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 20-September-2014

Revision date -

Version # 01

References 1) Arcabose Tablets, Package Insert, Roxane Laboratories, Inc. , Columbus, Ohio.

2) PDR – Physicians Desk Reference.

3) Ariel Webinsight. Regulatory and ChemExpert Database.

Disclaimer

Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.