

1. Identification

Product Name: Glyburide Tablets, USP 1.25 mg, 2.5 mg, 5 mg

Product Information: Glyburide Tablets, USP

Company Name: Cadila Pharmaceuticals Limited

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2. HAZARD(S) IDENTIFICATION

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Antidiabetic drug: has blood-sugar lowering properties.

Long Term: Individuals sensitive to this chemical or other materials in its chemical class may
Develop allergic reactions.

Known Clinical Effects: Adverse effects associated with therapeutic use include decreased blood sugar (hypoglycemia), yellowing of the skin, eyes, and mucous membranes (jaundice), nausea, epigastric discomfort, heartburn and skin reaction. Clinical use has caused effects on the cardiovascular system, including cardiovascular mortality.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not

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apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS**Chemical Name:** 1-[[p-[2-(5-Chloro-o-anisamido) ethyl] phenyl] sulfonyl]-3-cyclohexylurea**Product Code:** Not applicable**Hazardous Ingredients / Components:** Not Applicable**CAS No.:** 10238-21-8**Other Components:**

Inactive Ingredients	Exposure Limit	CAS No.
Microcrystalline Cellulose	Not Found	9004-34-6
Pregelatinized Starch	Not Found	9005-84-9
Sodium Starch Glycolate	Not Found	9063-38-01
Magnesium Stearate	Not Found	557-04-0
FD&C Yellow # 6	Not Found	2783-94-0
D&C Yellow # 10	Not Found	8004-92-0
FD&C Blue # 1	Not Found	3844-45-9

4. FIRST – AID MEASURES**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Protective Equipment: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Specific Hazards: Not Applicable

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Environmental precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Method for cleaning up: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

7. HANDLING AND STORAGE

Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage: Store at 20° to 25°C (68° to 77°F)] in a dry place. Dispense in a well-closed container as defined in the USP.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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Engineering measures: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Respiratory Protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Eye Protection: Wear safety glasses or goggles if eye contact is possible.

Personal protective equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Skin Protection: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Glyburide Tablets, USP 1.25 mg

White to off-white, round, bi-convex, compressed tablets engraved with “C 13” on one side and horizontal bisect on other side.

Glyburide Tablets, USP 2.5 mg

Peach to light-peach colored, round, bi-convex, compressed tablets engraved with “C 12” on one side and horizontal bisect on other side.

Glyburide Tablets, USP 5 mg

Green to light-green colored, round, bi-convex, compressed tablets engraved with “C 11” on one side and horizontal bisect on other side.

Odour: Odourless

PH (Value):Not Applicable

Boiling Point: Not Applicable

Melting Point: Not Applicable

Flash Point: Not Applicable

Flammable Limits: Not Applicable

Auto Ignition Temperature: Not Applicable

Explosive Properties: Not Applicable

Oxidising Properties: Not Applicable

Vapour Pressure (mm Hg): Not Applicable

Density (g/ml): Not Applicable

Solubility (Water): Not Applicable

Solubility (Other): Not Applicable

Partition Coefficient: Not Applicable

Other Information: Glyburide Tablets, is a White or almost white crystalline powder. Practically insoluble in water, sparingly soluble in Methylene Chloride, Slightly soluble in Alcohol and in Methanol.

10. STABILITY AND REACTIVITY

Hazardous Reactions: No data available.

Stable: Stable under normal ambient and anticipated storage and handling conditions.

Hazardous Decomposition Product(s): Not Applicable

Conditions to avoid: Avoid exposure to extreme heat, light and moisture.

Materials to avoid: Not Applicable

11. TOXICOLOGY INFORMATION

General: The information included in this section describes the potential hazards of the individual ingredients.

Target organ: Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Inhalation (LC50): Not Applicable

Skin Contact (Dermal – LD50): Not Applicable

Eye Contact: Not Applicable

Ingestion (Oral – LD50): Not Applicable

12. ECOLOGICAL INFORMATION

No data available on Ecotoxicity

13. DISPOSAL CONSIDERATIONS

Dispose the waste in accordance with all applicable Federal, State and local laws.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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Classification and labeling Danger symbol: Not Applicable**Danger Label:** Not Applicable**Safety phrases:** Not Applicable**16. OTHER INFORMATION**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this SDS.

End of Safety Data Sheet