Section 1. Identification

1.1 Substance Name: Nitroglycerin Sublingual Tablets

1.2 Relevant identified uses of the substance or mixture and uses advised against:
Pharmaceutical product for the treatment of angina pectoris

1.3 Company Identification: Glenmark Pharmaceuticals Inc., USA

750 Corporate Drive

Mahwah, NJ 07430

1.4 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS
Acute Oral Toxicity: Category 4
Acute Toxicity - Dusts and Mists: Category 4
Specific target organ systemic toxicity (repeated exposure): Category 2

EU Classification:
EU Indication of danger: Toxic

2.2 Label elements



Signal Word: Warning

2.3 Risk Phrase:
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R33 - Danger of cumulative effects

Statement of Hazard:
H304 - May be fatal if swallowed and enters airways
H332 - Harmful if inhaled
H373 - May cause damage to organs through prolonged or repeated exposure: cardiovascular

2.4 Safety Advice:
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P314 - Get medical attention/advice if you feel unwell
P501 - Dispose of contents/container in accordance with all local and national regulations

2.3 Other hazards:
Australian Hazard Classification (NOHSC):
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 product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3- Composition/Information on Ingredients

3.1 Substances

Sr No	Ingredients	CAS No.	0.3mg strength % composition	0.4mg strength % composition	0.6mg strength % composition
1	Diluted Nitroglycerin (2 %w/w Nitroglycerin in lactose)	55-63-0	0.75	1	1.5
2	Glyceryl Behenate	Not Known	Proprietary	Proprietary	Proprietary
3	Starch 1500 (Pregilatinized Starch)	9005-25-8	Proprietary	Proprietary	Proprietary
4	Lactose Monohydrate (Pharmatose 200M)	64044-51-5	Proprietary	Proprietary	Proprietary
5	Hydrophobic Colloidal Silica ((Aerosil@ R972 Pharma)	Not Known	Proprietary	Proprietary	Proprietary
6	Croscarmellose Sodium (Ac-Di-Sol SD-711)	Not Known	Proprietary	Proprietary	Proprietary
7	Calcium Stearate	1592-23-0	Proprietary	Proprietary	Proprietary

Section 4. First aid Measures

4.1 Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

4.2 Skin: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

4.3 Eyes: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

4.4 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.

4.5 Most important symptoms and effects, both acute and delayed
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Section 5. Fire-fighting Measures

5.1 General Information: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

5.2 Extinguishing Media: Use carbon dioxide, dry chemical, or water spray

5.3 Fire/Explosion Hazard: Formation of toxic gases is possible during heating or fire.

5.4 NFPA Rating: Not Known

Section 6. Accidental Release Measures

6.1 General Information: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel

6.2 Major/Minor Spills: 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. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release

Section 7. Handling and Storage

7.1 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 hands and any exposed skin after removal of PPE. 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.

7.2 Storage: Store as directed by product packaging.

7.3 Storage incompatibility: Keep away from direct sunlight

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Components with workplace control parameters

Exposure limits	Issuer	OEL
Compound Nitroglycerin	ACGIH (TWA)	0.05 PPM

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route

8.2 Exposure controls:

Appropriate engineering controls
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

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

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

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

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

Respiratory protection: 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

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	White tablet
Colour	:	White
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known

Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron)	:	Not Known

9.2 Other Information

Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Not Known

10.2 Chemical stability: Stable under normal conditions of use.

10.3 Conditions to Avoid: Heat, moisture

10.4 Incompatibilities with Other Materials: As a precautionary measure, keep away from strong oxidizers.

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

10.6 Hazardous Polymerization: Will not occur under.

Section 11. Toxicological Information

11.1 Information on toxicological effects

Acute Toxicity

	Dose	Route	Species	Dosage
Nitroglycerin	LD50	Oral	Rat	105 mg/kg
	LD50	Oral	Mouse	115 mg/kg
	LD50	Dermal	Rabbit	>280 mg/kg
	LD50	Dermal	Rat	>29 mg/kg
	LD50	IV	Rat	23.2 mg/kg

Section 12. Ecological Information

12.1 Toxicity: Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Nitroglycerin
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 1.91 mg/L

In Vitro Cytogenetics Rat Negative
Midge LC50 48 Hours 20 mg/L

12.2 Persistence and degradability: Not Known

12.3 Bioaccumulative potential: Not Known

12.4 Mobility in soil: Not Known

12.5 Other: Not Known.

Section 13. Disposal Considerations

13.1 Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14. Transport Information

14. 1 Special precautions for user:

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Canada - WHMIS: Classifications WHMIS hazard class:
Class D, Division 2, Subdivision B

Nitroglycerin

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb 4.54 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-240-8

Section 16. Additional Information

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Explosives-Unstable explosives; H200 - Unstable explosive
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects
E - Explosive
T+ - Very toxic
N - Dangerous for the environment
R 3 - Extreme risk of explosion by shock, friction, fire or other sources of ignition.
R33 - Danger of cumulative effects.

R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Revision: First revision due to change in Section 3 & 8 and Second revision due to change in Title name.

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
Sanjeet 20-09-2017	20/09/2017
Signature /Date	Signature /Date