SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Tenth Revised Edition UNITED NATIONS New York and Geneva, 2023

NITROGLYCERIN SUBLINGUAL TABLETS USP 0.3MG, 0.4MG AND 0.6MG

1. IDENTIFICATION

GHS Product identifier: NITROGLYCERIN SUBLINGUAL TABLETS
Product code: #

Chemical Description: 1,3-dinitrooxypropan-2-yl nitrate
Recommended use of the chemical: Vasodilatory drug used primarily to provide relief from anginal chest pain.

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: L74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Skin sensitization	1	Dermal
STOT SE	2 (0.6 mg)	
STOT RE	2 (0.6 mg)	
Reproductive toxicity	2	

Labeling
Globally Harmonized System, UN (GHS)

Classification	
Signal Word	**Warning**
Hazard Statements:	H302 Harmful if swallowed H332 - Harmful if inhaled H317- May cause allergic skin reaction H373 - May cause damage to organs through prolonged or repeated exposure: cardiovascular H361 – Suspected of damaging fertility of the unborn child

Precautionary Statements:	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 P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. 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 P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P311: Call a poison centre/physician P391: Collect spillage
Other hazards	Control formation and generating of dusts during use.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Nitroglycerin

Hazardous ingredients	**CAS**	**Content**		
		0.3 mg	**0.4 mg**	**0.6 mg**
Diluted Nitroglycerin	*55-63-0 (Nitroglycerin), 10039-26-6 (lactose monohydrate)*	0.6%	0.8%	1.2%
Lactose Monohydrate	64044-51-5	-		
Pregelatinized starch	9005-25-8	-		
Hydrogenated vegetable oil	68334-00-9	-		
Colloidal silicon Dioxide	112945-52-5, 7631-86-9	-		
Calcium Stearate	1592-23-0	-		
This product is a mixture of chemical substances. The specific chemical % for other chemical ingredients of this product is being withheld as it is Propriety information.				

4. FIRST-AID MEASURES

Inhalation

Move the person into fresh air. In case of respiratory symptoms, place the person in a semi-seated position and administer oxygen. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Never give anything by mouth to an unconscious person. DO not induce emesis. Rinse mouth with water. Consult a physician.

Establish a patent airway. Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for shock and treat if necessary. Anticipate seizures and treat as necessary.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use plenty of water. If water is not available, use alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

Fire may produce irritating, corrosive and/or toxic gases

Specific hazards arising from the chemical

Vapors may form explosive mixtures with air.

- Vapors may travel to source of ignition and flash back.
- Most vapors are heavier than air. They will spread along the ground and collect in low or confined areas (sewers, basements, tanks, etc.).

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary

Special exposure hazards

Inhalation or contact with material may irritate or burn skin and eyes.

- Fire may produce irritating, corrosive and/or toxic gases.
- Vapors may cause dizziness or asphyxiation.
- Runoff from fire control or dilution water may cause environmental contamination.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed. Store at 25 °C

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	ACGIH	STEL	Source
. *55-63-0*	Nitroglycerin	TWA 0.05 ppm	-	-
	Calcium stearate	TWA 10 mg/m^3		
	Pregelatinised starch	TWA 10 mg/m^3	-	-

Occupational exposure controls
Appropriate engineering controls
Maintain air concentrations below occupational exposure standards. Prevent dust formation. Local exhaust ventilation backed up by good general ventilation should be installed.

General Personal Protection
Goggles, gloves, protective clothing, to prevent skin and eye contact
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.
Hand protection
Protective gloves. Hand protection should be made from nylon or polyethylene with sweat-absorbent cotton liner.
Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White Tablets
Form: Tablets
Odour: None
pH: Not available
Melting point: Not known
Boiling point: Not applicable
Flash point: Not applicable
Flammability (solid): Flammable/combustible material. Extremely sensitive to shock and rapid heating.
Vapour pressure: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Density: Not available
Solubility in solvents: Not known
n-Octanol/Water Partition Coefficient: Not known
Viscosity: Not applicable
Oxidizing properties: Not applicable
Explosivity: May be ignited by Shock, heat, sparks or flames.
Decomposes at 60 °C and explodes at 218 °C

The active ingredient in this formulation is highly explosive. However, based on the amount of active ingredient contained in this product it is not expected to pose an explosion risk.

10. STABILITY AND REACTIVITY

Conditions to avoid

Avoid moisture

Materials to avoid

Keep away from strong Oxidizing agents. Airborne particles/dust may fuel fire/explosion in presence of source of ignition. Keep away from direct sunlight.

Hazardous decomposition products

In event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

Possible combustion products are Carbon oxides, nitrogen oxides, hydrochloric acid.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Nitroglycerin

Rat Oral LD_{50} 105 mg/kg
Mouse Oral LD_{50} 115 mg/kg
Rabbit Dermal LD_{50} > 280 mg/kg
Rat Dermal LD_{50} > 29 mg/kg
Rat IV LD_{50} 23.2 mg/kg

Based on the data, nitroglycerin mixture is not classified for acute oral toxicity

Primary Irritation

Skin: Nitroglycerin active ingredient is not classified for skin or eye irritation.
GHS classification is not applicable for skin or eye irritation.

Respiratory or Skin sensitization

Nitroglycerin substance is category 1 for skin sensitization and hence mixture is classifiable for skin sensitization in category 1.

CMR consideration:

Germ cell mutagenicity:

- Data not sufficient for classification.

GHS Classification is not possible.

Carcinogenicity

Not classifiable as human carcinogen.

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
GHS Classification for active ingredient is not possible due to lack of data.

Reproductive toxicity

Fertility and Embryonic Development
Rat Oral 434 mg/kg/day NOAEL Negative
Embryo / Fetal Development
Rabbit Oral 240 mg/kg/day NOAEL Not Teratogenic
Nitroglycerin substance is classified as category 2 and hence tablets fall under category 2. Label is not needed.

Specific target organ toxicity single exposure: (STOT SE)

Nitroglycerin - Category 1 (cardiovascular system, blood)

0.6 mg Nitroglycerin tablets - category 2.
0.3 and 0.4 mg tablets are not classifiable.

Specific target organ toxicity repeated exposure:

Nitroglycerin - Category 1 (cardiovascular system)

0.6 mg Nitroglycerin tablets - category 2.
0.3 and 0.4 mg tablets are not classifiable.

Aspiration hazard:
GHS Classification is not possible.

Additional information: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

Rate of biodegradation in soil is unknown.

Based on a classification scheme, an estimated Koc value of 180, determined from a log Kow of 1.62 and a regression-derived equation, indicates that nitroglycerin is expected to adsorb to suspended solids and sediments.

Potential for bioconcentration in aquatic organisms is low.

An estimated BCF of 4 was calculated for nitroglycerin. This BCF suggests the potential for bioconcentration in aquatic organisms is low.

Nitroglycerin
Lepomis macrochirus (Bluegill Sunfish)
LC_{50} 96 Hours 1.91 mg/L
Midge LC_{50} 48 Hours 20 mg/L

Mixture is not classified for aquatic toxicity.

Persistence and degradability
Biodegradation – 0% (biotic, 28 d)

Behaviour in treatment plants
Data not available. GHS Classification is not possible.

Additional information
Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal
Product residues should be considered as hazardous waste. Disposal must be done through authorised waste disposal firms in compliance with local regulations. Waste should not be released to sewers.

Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

This substance is not classified as dangerous for transport.
Not regulated for transport of dangerous goods: DOT, IATA, IMDG

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2023 as amended.
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2019

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 06/01/24