

Safety Data Sheet

1. IDENTIFICATION

Products: Isosorbide Mononitrate Extended Release Tablets 30 mg, 60 mg and 120 mg
Oxycodone Hydrochloride Tablets 10mg


Recommended Use of the Chemical and Restrictions On Use: Pharmaceutical Product, Prevention of angina pectoris.

Manufacturer: Neshor Pharmaceuticals (USA) LLC
13910 St Charles Rock Road
Earth City, MO. 63044
Phone: 314-209-4700

Emergency Phone Number: 314-209-4700

2. HAZARDS IDENTIFICATION

Classification:

Health	Environmental	Physical
Eye Irritation Category 2A Skin Irritation Category 2	None	None
GHS Label		
		
<p>WARNING! Causes skin irritation. Causes serious eye irritation.</p> <p>Prevention: Wash hands thoroughly with soap and water after handling damaged tablets. Wear protective gloves and eye protection for handling damaged tablets.</p>	<p>Response: IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical attention. Take off contaminated clothing and wash it before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.</p>	

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	Amount
Isosorbide-5-Mononitrate	16051-77-7	20-55%
Non-Hazardous Ingredients	Mixture	45-80%

Note: The exact percentage is withheld as a trade secret

4. FIRST AID MEASURES

Solid tablets are coated with a non-hazardous coating. Handling them will not cause adverse health effects. The following first aid applies to contact with broken tablets.

Eye: Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Remove contact lenses if present and easy to do. Get medical attention if irritation persists.

Skin: Wash skin thoroughly with soap and water after handling broken or damaged tablets. Get medical attention if irritation develops and persists. Remove and launder contaminated clothing before reuse.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Get immediate medical attention for overdose.

Inhalation: Remove victim to fresh air. Get medical attention if irritation or other symptoms persist.

Most important symptoms/effects, acute and delayed: This product is a vasodilator. Inhalation or swallowing may cause severe hypotension (low blood pressure), headache, light headedness and shortness of breath. Contact with damaged tablets may cause eye and skin irritation.

Indication of immediate medical attention and special treatment needed, if necessary: Seek immediate medical treatment for ingestion overdose or significant inhalation of dust from crushed tablets.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Use water spray or fog, dry chemical, CO₂ or foam. Do not use straight water streams if large amounts of dust are present.

Specific Hazards Arising from the Chemical: Isosorbide-5-Mononitrate is a flammable solid. High concentrations of dust that may be present if tablets are crushed or damaged may present a serious fire and explosion hazard. Intact tablets may burn vigorously under fire conditions. Combustion products may be toxic and include oxides of carbon and nitrogen.

Special Protective Equipment and Precautions for Fire-Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: Wear appropriate protective clothing as described in Section 8. Eliminate sources of ignition. Avoid contact and inhalation of dust if present.

Methods and Materials for Containment and Cleaning Up: Carefully sweep up or shovel, avoiding creating airborne dust. Use non-sparking tools and equipment. Use caution to prevent damaging intact tablets. If a vacuum is used, explosion-proof equipment is required. Place in appropriate containers for disposal. Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Do not crush or break tablets. Avoid processes that generate dust. Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Handle with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Follow good housekeeping procedures to minimize the accumulation of combustible dusts on surfaces, including overhead surfaces. High concentrations of dust may present a serious fire and explosion hazard.

Conditions for Safe Storage, including any incompatibilities: Store in a dry area. Store away from acids, bases and oxidizers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines:

Isosorbide-5-Mononitrate	None Established
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Appropriate Engineering Controls: No special controls are required for handling undamaged tablets. If tablets are damaged, use adequate general or local exhaust ventilation to minimize exposure levels. If dust is generated in handling, explosion-proof equipment is required.

Respiratory Protection: No respiratory protection is required for handling undamaged tablets. If tablets are damaged and dust is present, a NIOSH approved respirator with particulate filters or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with OSHA 1910.134 and good industrial hygiene practice.

Skin Protection: Wear impervious gloves such as rubber or neoprene to avoid skin contact when handling tablets. Wear protective clothing as needed to avoid skin contact and prevent contamination of personal clothing.

Eye Protection: Chemical safety goggles or safety glasses recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Tablets, white, yellow or pink.	Odor: None
Viscosity: Not applicable	Odor Threshold: Not applicable
Vapor Density: Not applicable	Boiling Point/Range: Not applicable
Solubilities: Partially soluble in water	Vapor Pressure: Not applicable
Relative Density: Not determined	Evaporation Rate: Not applicable
Melting Point/Freezing Point: Not determined	pH: Not applicable
Decomposition Temperature: Not determined	Partition Coefficient(n- Octanol/Water): Not determined
Flashpoint: None	Autoignition Temperature: Not applicable
Flammable Limits: LFL: Not applicable UFL: Not applicable	Flammability (solid, gas): No applicable data available

10. STABILITY AND REACTIVITY

Reactivity: Not considered reactive.

Chemical Stability: Stable under normal storage and handling conditions.

Possibility of Hazardous Reactions: May react with strong oxidizers generating heat.

Conditions to Avoid: Avoid damaging tablets and creating dust.

Incompatible Materials: Strong acids, bases and oxidizers.

Hazardous Decomposition Products: Thermal decomposition or combustion will generate oxides of carbon and nitrogen.

11. TOXICOLOGICAL INFORMATION

Solid tablets are coated with a non-hazardous coating. Handling them will not cause adverse health effects. The following health effects apply to contact with broken tablets.

Ingestion: May be harmful if large amounts swallowed. This product is a vasodilator. Ingestion may cause severe hypotension (low blood pressure), headache, light headedness and shortness of breath.

Methemoglobinemia may also occur.

Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract and symptoms of overdose similar to ingestion.

Eye: May cause irritation of the eyes with redness and tearing.

Skin: May cause skin irritation.

Chronic Effects: None currently known.

Carcinogenicity: None of the components is listed as a carcinogen or suspected carcinogen by ACGIH, IARC, NTP or OSHA. Isosorbide mononitrate did not cause cancer in a study with rats at doses of up to 900 mg/kg/day for 6 months and 500 mg/kg/day for the remaining 212 weeks for males and 137 weeks for females. No evidence of carcinogenicity was observed in mice at a dose of 900 mg/kg/day for 104 weeks.

Reproductive Toxicity: No adverse effects have been observed in studies with isosorbide mononitrate in rats and rabbits at doses greater than 200 mg/kg/day.

Germ Cell Mutagenicity: Isosorbide mononitrate did not produce gene mutations (Ames test, mouse lymphoma test) or chromosome aberrations (human lymphocytes and mouse micronucleus tests) at biologically relevant concentrations.

Numerical Measures of Toxicity:

Isosorbide mononitrate: LD50 oral rat 2010 mg/kg

12. ECOLOGICAL INFORMATION

No data is currently available. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state and federal environmental regulations.

14. TRANSPORT INFORMATION

Transportation of Dangerous Goods Description:

Proper Shipping Name: Not regulated

UN Number: None

Hazard Class/Packing Group: None

Labels Required: None

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting. Many states have more stringent spill reporting requirements. Report spill in compliance with all federal, state and local requirements.

SARA TITLE III:

Hazard Category for Section 311/312: Acute Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to SARA Title III
Section 313 Reporting requirements: None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a drug and not subject to TSCA.

STATE REGULATIONS:

California Proposition 65: These products contain the following substances known to the State of California to cause cancer and/or reproductive harm: None known

16. OTHER INFORMATION

SDS Date of Preparation/Revision: March 22, 2013

DISCLAIMER

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