

Safety Data Sheet

1. IDENTIFICATION

Products: Morphine Sulfate Extended Release Tablets 15mg, 30 mg, 60 mg/kg


Recommended Use of the Chemical and Restrictions On Use: Pharmaceutical Product, Opioid Analgesic

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 |
|---|---------------|----------|
| Respiratory Sensitization – Category 1B Skin Sensitization – Category 1B Germ Cell Mutagenicity Category 2 Carcinogen Category 2 Reproductive Toxicity Category 1B Effects on or via Lactation Specific Target Organ Toxicity Single Exposure Category 3 (nervous system) | None | None |
| GHS Label <div style="text-align: center;">  </div> | | |
| Contains morphine sulfate and titanium dioxide DANGER! H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317 May cause an allergic skin reaction. H341 Suspected of causing genetic defects H351 Suspected of causing cancer by inhalation. H360 May damage the unborn child. H362 May cause harm to breast-fed children. H336 May cause drowsiness or dizziness. Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P261 Avoid breathing dust. P263 Avoid contact during pregnancy and while nursing. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. | | |
| Response: P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing. P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P362+P364 Take off contaminated clothing and wash it before reuse. P308+P313 IF exposed or concerned: Get medical advice. Storage: Store locked up. Disposal: P501 Dispose of contents/container to an approved waste disposal plant. | | |

| | |
|--|--|
| P271 Use only outdoors or in a well-ventilated area. P284 In case of inadequate ventilation wear respiratory protection. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves and protective clothing. | |
|--|--|

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Component | CAS No. | Amount |
|------------------|------------|--------|
| Morphine Sulfate | 6211-15-0 | 9-20% |
| Titanium Dioxide | 13463-67-7 | 1-2% |

Note: The exact percentage is withheld as a trade secret

4. FIRST AID MEASURES

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. Get medical attention if irritation or other symptoms develop and persist. 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 narcotic. Effects of exposure include dizziness, sleepiness, headache, nausea, difficulty in breathing, change in heart rate, respiratory depression and collapse.

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. Physicians should treat for narcotic overdose as appropriate.

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: High concentrations of dust that may be present if tablets are crushed or damaged may present a dust explosion hazard. Combustion products may be toxic and include oxides of carbon and sulfur compounds.

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 if dust from tablets is present.

Environmental precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and Materials for Containment and Cleaning Up: Carefully sweep up or shovel, avoiding creating airborne dust. An explosion-proof HEPA vacuum may also be used. Clean area thoroughly. Place in an appropriate containers for disposal. Handle spill residues as a controlled substance.

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 dust explosion hazard. Handle and store as a controlled substance.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines:

| | |
|------------------|--|
| Morphine Sulfate | 10 ug/m ³ TWA; 50 ug/m ³ STEL (manufacturer recommended) |
| Titanium Dioxide | 15 mg/m ³ TWA (total dust) OSHA PEL 10 mg/m ³ TWA (total dust) ACGIH TLV* |

Note: ACGIH has issued a notice of intended change to reduce the TLV to 1 mg/mg TWA (respirable dust).

Appropriate Engineering Controls: No special controls are required for handling undamaged tablets. If tablets are damaged, use with general or adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. 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, various colors. | Odor: None |
| Viscosity: Not applicable | Odor Threshold: Not applicable |
| Vapor Density: Not applicable | Boiling Point/Range: Not applicable |
| Solubilities: 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 bases, oxidizers, borax, ferric chloride, iodides, lead acetate, mercuric chloride, gold salts.

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

11. TOXICOLOGICAL INFORMATION

Ingestion: May be harmful if large amounts swallowed. This product is a narcotic drug. Overdosage may result in dizziness, sleepiness, headache, nausea, difficulty in breathing, change in heart rate, respiratory depression and collapse. Severe overdose may result in stopped breathing, circulatory collapse, low blood pressure and death. Morphine sulfate is addictive and prolonged use may cause dependence and tolerance with withdrawal symptoms on stopping the drug.

Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract and symptoms of overdose similar to ingestion. Inhalation of dust may cause allergic reaction with asthma symptoms in sensitized individuals.

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

Skin: May cause mild skin irritation. May cause an allergic skin reaction in sensitized individuals.

Chronic Effects: Repeat dose studies in animals have shown expected behavioral effects and effects on the lungs, kidney and bladder.

Carcinogenicity: Titanium dioxide is classified as a suspect carcinogen by IARC when inhaled as a respirable dust but not when ingested. None of the other components is listed as a carcinogen or suspected carcinogen by ACGIH, IARC, NTP or OSHA. No carcinogenicity data is available for morphine sulfate.

Reproductive Toxicity: Adverse effects have been observed in studies with morphine sulfate in laboratory animals. These effects include decreased litter size, decrease in brain weights, delayed motor and sexual maturation and increased neonatal mortality. Decreases in fertility have also been observed. In humans, chronic use during pregnancy has resulted in withdrawal symptoms, reversible reduction in brain volume, small size and increased risk of sudden infant death. Morphine sulfate is excreted in breast milk and can result in adverse effects on nursing children.

Germ Cell Mutagenicity: Morphine sulfate has produced mixed results in laboratory assays. It was negative in in-vitro mouse chromosome aberration and the drosophila dominant lethal assay but positive in the in-vivo mouse micronucleus assay and in-vivo mouse lymphocyte chromosome aberration assay.

Numerical Measures of Toxicity:

Morphine Sulfate: LD50 oral rat 461 mg/kg

Titanium Dioxide: No data available

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, Chronic 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: October 17, 2013

DISCLAIMER

The information in this SAFETY DATA SHEET should be provided to all who will use, handle, store, transport, or otherwise be exposed to this material. This information has been prepared for the guidance of plant engineering, operations, and management, and for persons working with or handling this material. Neshor Pharmaceuticals (USA) LLC believes this information to be reliable and up-to-date as of the date of publication, but makes no warranty that it is.