



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

KING PHARMACEUTICALS, INC.

501 Fifth Street

Bristol, TN 37620

EMERGENCY TELEPHONE

NUMBER: 1-800-776-3637

TECHNICAL ASSISTANCE:

1-800-776-3637

SUBSTANCE: AVINZA® EXTENDED RELEASE CAPSULES CII

TRADE NAMES/SYNONYMS:

NDC#: 60793-605-01 (30 mg); NDC#. 60793-603-01 (45mg); NDC#: 60793-606-01 (60 mg); NDC#. 60793-604-01 (75mg); NDC#: 60793-607-01 (90 mg); NDC#: 60793-608-01 (120 mg); AVINZA® MORPHINE SULFATE EXTENDED RELEASE CAPSULES CII; 00232467

CHEMICAL FAMILY: opioid

PRODUCT USE: analgesic for relief of moderate to severe pain

CREATION DATE: Feb 13 2007

REVISION DATE: Dec 15 2008

2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: MORPHINE SULFATE PENTAHYDRATE

CAS NUMBER: 6211-15-0

PERCENTAGE: 30, 45, 60, 75, 90, or 120 mg/capsule

COMPONENT: INERT INGREDIENTS

CAS NUMBER: Not assigned.

PERCENTAGE: balance

3. HAZARDS IDENTIFICATION

NFPA RATINGS (SCALE 0-4): HEALTH=1 FIRE=1 REACTIVITY=0

EMERGENCY OVERVIEW:

COLOR: various colors

PHYSICAL FORM: capsule

MAJOR HEALTH HAZARDS: This product will cause central nervous system depression. Because Avinza capsules are a modified, extended-release formulation of morphine sulfate, they should never be crushed or dissolved due to risk of rapid release and absorption of a potentially fatal dose of morphine. Consumption of



alcohol in any form must also be avoided during Avinza therapy. This includes avoiding alcoholic beverages as well as any medication, prescription or non-prescription, which contains alcohol. Consumption of alcohol while taking Avinza may result in the rapid release and absorption of a potentially fatal dose of morphine.

PHYSICAL HAZARDS: Dust/air mixtures may ignite or explode.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: irritation, allergic reactions, changes in blood pressure, nausea, vomiting, constipation, difficulty breathing, headache, drowsiness, dizziness, fainting, mood swings, dilated pupils or pin-point pupils

LONG TERM EXPOSURE: allergic reactions, changes in blood pressure, nausea, vomiting, constipation, difficulty breathing, headache, drowsiness, dizziness, fainting, mood swings, dilated pupils or pin-point pupils

SKIN CONTACT:

SHORT TERM EXPOSURE: irritation, allergic reactions

LONG TERM EXPOSURE: allergic reactions

EYE CONTACT:

SHORT TERM EXPOSURE: irritation

LONG TERM EXPOSURE: no information on significant adverse effects

INGESTION:

SHORT TERM EXPOSURE: changes in blood pressure, nausea, vomiting, constipation, difficulty breathing, headache, drowsiness, dizziness, fainting, mood swings, dilated pupils or pin-point pupils

LONG TERM EXPOSURE: changes in blood pressure, nausea, vomiting, constipation, difficulty breathing, headache, drowsiness, dizziness, fainting, mood swings, dilated pupils or pin-point pupils

4. FIRST AID MEASURES

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

SKIN CONTACT: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

EYE CONTACT: Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

INGESTION: If swallowed, get medical attention.

NOTE TO PHYSICIAN: For inhalation, consider oxygen.

5. FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARDS: Slight fire hazard. Dust/air mixtures may ignite or explode.

EXTINGUISHING MEDIA: carbon dioxide, regular dry chemical, regular foam, water

FIRE FIGHTING: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

HAZARDOUS COMBUSTION PRODUCTS:

Thermal decomposition or combustion products: oxides of carbon, oxides of nitrogen, oxides of sulfur

6. ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers.

7. HANDLING AND STORAGE

STORAGE: Store and handle in accordance with all current regulations and standards. Store at 25 C. Excursions permitted to 15-30 C. Protect from light, moisture, and excessive heat. Store in a tightly closed container. Store in light resistant container. Store in a secure area. See original container for storage recommendations. Keep separated from incompatible substances.

HANDLING: Observe good hygiene and safety practices when handling this product. Wash thoroughly after handling. This product is a schedule II controlled substance. Handling, transfer, dispensing, and disposal must be done under Drug Enforcement Administration regulations applicable to controlled substances. Use methods to minimize dust.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

AVINZA® EXTENDED RELEASE CAPSULES CII:

No occupational exposure limits established.

VENTILATION: Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

EYE PROTECTION: Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Wear appropriate chemical resistant clothing.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use. Any air-purifying half-mask respirator equipped with organic vapor cartridge(s) in combination with an N95, R95, or P95 filter. The following filters may also be used: N99, R99, P99, N100, R100 or P100.

Any air-purifying full-facepiece respirator (gas mask) with a chin-style, front-mounted or back-mounted organic vapor canister having an N100, R100, or P100 filter.

Any powered, air-purifying respirator with a tight-fitting facepiece, organic vapor cartridge(s) and high-efficiency particulate filter(s).

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.

For Unknown Concentrations or Immediately Dangerous to Life or Health -

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: solid

COLOR: various colors

PHYSICAL FORM: capsule

ODOR: Not available

BOILING POINT: Not applicable

MELTING POINT: Not available

VAPOR PRESSURE: Not applicable

VAPOR DENSITY: Not applicable

SPECIFIC GRAVITY: Not available

WATER SOLUBILITY: soluble

PH: Not applicable

VOLATILITY: Not applicable

ODOR THRESHOLD: Not available

EVAPORATION RATE: Not applicable

COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

10. STABILITY AND REACTIVITY

REACTIVITY: Stable at normal temperatures and pressure.

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

INCOMPATIBILITIES: oxidizing materials, acids, alkalis, chlorates, chlorides, iodides, lead acetate, permanganates

HAZARDOUS DECOMPOSITION:

Thermal decomposition or combustion products: oxides of carbon, oxides of nitrogen, oxides of sulfur

POLYMERIZATION: Will not polymerize.

11. TOXICOLOGICAL INFORMATION

AVINZA® EXTENDED RELEASE CAPSULES CII:

ADDITIONAL DATA: Interactions with drugs may occur. May impair performance of tasks requiring alertness. This substance, by all routes of administration, has been associated with episodes of abuse.

MORPHINE SULFATE PENTAHYDRATE:

TOXICITY DATA: 973 mg/kg oral-rat LD50

ACUTE TOXICITY LEVEL:

Moderately Toxic: ingestion

TARGET ORGANS: central nervous system

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: blood system disorders, hormonal disorders, respiratory disorders, gastrointestinal disorders

ADDITIONAL DATA: Alcohol may enhance the toxic effects. Interactions with drugs may occur. May impair performance of tasks requiring alertness. May be excreted in breast milk. May cross the placenta. Abrupt cessation of use by patients with physical dependence may result in symptoms of withdrawal.

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations. Disposal of controlled substances must be consistent with state and federal regulations.

14. TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: No classification assigned.

15. REGULATORY INFORMATION

U.S. REGULATIONS:

CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4): Not regulated.

SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355 Subpart B): Not regulated.

SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355 Subpart C): Not regulated.

SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370 Subparts B and C):

ACUTE: Yes

CHRONIC: No

FIRE: No

REACTIVE: No

SUDDEN RELEASE: No

SARA TITLE III SECTION 313 (40 CFR 372.65): Not regulated.

OSHA PROCESS SAFETY (29 CFR 1910.119): Not regulated.

STATE REGULATIONS:

California Proposition 65: Not regulated.

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): This product is exempt.

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

16. OTHER INFORMATION

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