



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: EMBEDA(TM) (morphine sulfate and naltrexone hydrochloride) Extended Release Capsules for oral use - CII

TRADE NAMES/SYNONYMS:

EMBEDA (TM) Capsules contain pellets of morphine sulfate and naltrexone hydrochloride at a ratio of 100:4. EMBEDA (TM) Capsule strengths; NDC numbers: 20mg/0.8mg NDC#60793-430-01; 30mg/1.2mg NDC#60793-431-01; 50mg/2mg NDC# 60793-433-01; 60mg/2.4mg NDC# 60793-434-01; 80mg/3.2mg NDC#60793-435-01; 100mg/4mg NDC#60793-437-01; 00233361

PRODUCT USE: An extended release oral formulation of morphine sulfate and naltrexone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

CREATION DATE: Jan 23 2009

REVISION DATE: Feb 20 2009

2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: MORPHINE SULFATE

CAS NUMBER: 64-31-3

PERCENTAGE: Proprietary

COMPONENT: NALTREXONE HYDROCHLORIDE

CAS NUMBER: 16676-29-2

PERCENTAGE: Proprietary

COMPONENT: TALC, NON-ASBESTOS FORM

CAS NUMBER: 14807-96-6

PERCENTAGE: Proprietary

COMPONENT: ETHANAMINIUM, N,N,N-TRIMETHYL-2-((2-METHYL-1-OXO-2-PROPENYL)OXY) ETHANAMINIUM CHLORIDE, POLYMER WITH ETHYL 2-PROPENOATE AND METHYL 2-METHYL-2-PROPENOATE

CAS NUMBER: 33434-24-1

PERCENTAGE: Proprietary

COMPONENT: NON-PAREILS

CAS NUMBER: Not assigned.

PERCENTAGE: Proprietary

COMPONENT: ETHYLCELLULOSE

CAS NUMBER: 9004-57-3

PERCENTAGE: Proprietary

COMPONENT: SODIUM CHLORIDE

CAS NUMBER: 7647-14-5

PERCENTAGE: Proprietary

COMPONENT: POLYETHYLENE GLYCOL

CAS NUMBER: 68130-99-4

PERCENTAGE: Proprietary

COMPONENT: HYDROXYPROPYL CELLULOSE

CAS NUMBER: 9004-64-2

PERCENTAGE: Proprietary

COMPONENT: DIBUTYL SEBACATE

CAS NUMBER: 109-43-3

PERCENTAGE: Proprietary

COMPONENT: METHACRYLIC ACID COPOLYMER

CAS NUMBER: 79-41-4

PERCENTAGE: Proprietary

COMPONENT: DIETHYL PHTHALATE

CAS NUMBER: 84-66-2

PERCENTAGE: Proprietary

COMPONENT: MAGNESIUM STEARATE

CAS NUMBER: 557-04-0

PERCENTAGE: Proprietary

COMPONENT: SODIUM DODECYL SULFATE, HPCE GRADE

CAS NUMBER: Not assigned.

PERCENTAGE: Proprietary

COMPONENT: ASCORBIC ACID

CAS NUMBER: 134-03-2

PERCENTAGE: Proprietary

3. HAZARDS IDENTIFICATION

NFPA RATINGS (SCALE 0-4): HEALTH=2 FIRE=1 REACTIVITY=0

EMERGENCY OVERVIEW:

COLOR: EMBEDA™ Capsules contain creamy white to light tan spheroidal pellets in various capsule sizes and colors for each strength (20 mg/0.8 mg: size 4, two-toned, yellow; 30 mg/1.2 mg: size 3, two-toned, blue violet; 50 mg/2 mg: size 1, two-toned, blue; 60 mg/2.4 mg: size 0, two-toned, pink; 80



mg/3.2 mg: size 0, two-toned, light peach; 100 mg/4 mg size 00, two-toned, green).

PHYSICAL FORM: capsule

MAJOR HEALTH HAZARDS: Are those associated with acute overdosage with morphine and include respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and sometimes, pulmonary edema, bradycardia, hypotension, and death. Marked mydriasis rather than miosis may be seen due to severe hypoxia in overdose situations.

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

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: same as effects reported in short term exposure ingestion

LONG TERM EXPOSURE: same as effects reported in long term exposure ingestion

SKIN CONTACT:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

EYE CONTACT:

SHORT TERM EXPOSURE: mechanical irritation

LONG TERM EXPOSURE: no information on significant adverse effects

INGESTION:

SHORT TERM EXPOSURE: abdominal pain, anorexia, anxiety, arthralgia, chills, constipation, depression, diarrhea, dizziness, dry mouth, dyspepsia, edema peripheral, flatulence, hot flush, hyperhidrosis, fatigue, headache, irritability, lethargy, loss of appetite, muscle spasms, nausea, pruritus, restlessness, sedation, sleep disturbances, somnolence, stomach discomfort, tremors, vomiting,

LONG TERM EXPOSURE: same as effects reported in short term exposure

4. FIRST AID MEASURES

INHALATION: It is unlikely that emergency treatment will be required. If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

SKIN CONTACT: It is unlikely that emergency treatment will be required. 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: It is unlikely that emergency treatment will be required. Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention if needed.

INGESTION: It is unlikely that emergency treatment will be required if used as directed. If adverse events occur, get medical attention.

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.

6. ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Notify Local Emergency Planning Committee and State Emergency Response Commission for release greater than or equal to RQ (U.S. SARA Section 304). If release occurs in the U.S. and is reportable under CERCLA Section 103, notify the National Response Center at (800)424-8802 (USA) or (202)426-2675 (USA).

7. HANDLING AND STORAGE

STORAGE: Store and handle in accordance with all current regulations and standards. Avoid generating dust. Store at 25 C. Store in a tightly closed container. Store in light resistant container. 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. 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:

EMBEDA(TM) (morphine sulfate and naltrexone hydrochloride) Extended Release Capsules for oral use - 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: EMBEDA™ Capsules contain creamy white to light tan spheroidal pellets in various capsule sizes and colors for each strength (20 mg/0.8 mg: size 4, two-toned, yellow; 30 mg/1.2 mg: size 3, two-toned, blue violet; 50 mg/2 mg: size 1, two-toned, blue; 60 mg/2.4 mg: size 0, two-toned, pink; 80 mg/3.2 mg: size 0, two-toned, light peach; 100 mg/4 mg size 00, two-toned, green).

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: Not available

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

HAZARDOUS DECOMPOSITION:

Thermal decomposition products: oxides of carbon

POLYMERIZATION: Will not polymerize.

11. TOXICOLOGICAL INFORMATION

EMBEDA(TM) (morphine sulfate and naltrexone hydrochloride) Extended Release Capsules for oral use - CII:

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to morphine, morphine salts, naltrexone, any situation where opioids are contraindicated; including respiratory depression, impaired pulmonary function, paralytic ileus and any situation where opioids should be used with caution such as respiratory disorders, gastrointestinal disorders, liver and/or kidney disorders, central nervous system disorders.

ADDITIONAL DATA: Interactions with drugs may occur. May be excreted in breast milk. This substance has been associated with episodes of abuse.

MORPHINE SULFATE:

TOXICITY DATA: 461 mg/kg oral-rat LD50

ACUTE TOXICITY LEVEL:

Toxic: ingestion

TARGET ORGANS: central nervous system

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to morphine, morphine salts, or any situation where opioids are contraindicated; including respiratory depression, impaired pulmonary function, paralytic ileus and any situation where opioids should be used with caution such as respiratory disorders, gastrointestinal disorders, liver and/or kidney disorders, central nervous system disorders.

MUTAGENIC DATA: Available.

REPRODUCTIVE EFFECTS DATA: Available.

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

NALTREXONE HYDROCHLORIDE:

TOXICITY DATA: 1450 mg/kg oral-rat LD50

ACUTE TOXICITY LEVEL:

Moderately Toxic: ingestion

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: May cause withdrawal in persons taking opioids

MUTAGENIC DATA: Available.

REPRODUCTIVE EFFECTS DATA: Available.

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):

DIETHYL PHTHALATE: 1000 LBS RQ

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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