# SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier
- **Material Name:** Morphine Sulfate Extended-Release with Sequestered Naltrexone Hydrochloride Capsules
- **Trade Name:** EMBEDA
- **Synonyms:** EMBEDA CII; EMBEDA® (morphine sulfate and naltrexone hydrochloride) extended -release capsules, for oral use, CII
- **Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
- **Intended Use:** Pharmaceutical product used as opioid analgesic

### Details of the Supplier of the Safety Data Sheet

#### Pfizer Inc
- **Pfizer Pharmaceuticals Group**
- **235 East 42nd Street**
- **New York, New York 10017**
- **1-800-879-3477**

#### Pfizer Ltd
- **Ramsgate Road**
- **Sandwich, Kent**
- **CT13 9NJ**
- **United Kingdom**
- **+00 44 (0)1304 616161**

### Emergency telephone number:
- **CHEMTREC (24 hours): 1-800-424-9300**
- **International CHEMTREC (24 hours): +1-703-527-3887**

### Contact E-Mail:
- pfizer-MSDS@pfizer.com

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture
- **GHS - Classification**
  - Germ Cell Mutagenicity: Category 2
  - Reproductive Toxicity: Category 1B
- **Effects on or via lactation**

### Label Elements
- **Signal Word:** Danger
- **Hazard Statements:**
  - H360D - May damage the unborn child
  - H341 - Suspected of causing genetic defects
  - H362 - May cause harm to breast-fed children

### Precautionary Statements:
- P202 - Do not handle until all safety precautions have been read and understood
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

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PZ02074
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
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<tr>
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Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16
4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
7. HANDLING AND STORAGE

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Dibutyl sebacate
- Latvia OEL - TWA: 10 mg/m³
- Lithuania OEL - TWA: 10 mg/m³

Sodium lauryl sulfate
- Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)
- 2 mg/m³

Australia TWA
- 2.5 mg/m³

Austria OEL - MAKs
- 2 mg/m³

Belgium OEL - TWA
- 2 mg/m³

Bulgaria OEL - TWA
- 1.0 fiber/cm³
- 6.0 mg/m³
- 3.0 mg/m³

Czech Republic OEL - TWA
- 2.0 mg/m³

Denmark OEL - TWA
- 0.3 fiber/cm³

Finland OEL - TWA
- 0.5 fiber/cm³

Greece OEL - TWA
- 10 mg/m³
- 2 mg/m³

Hungary OEL - TWA
- 2 mg/m³

Ireland OEL - TWAs
- 10 mg/m³
- 0.8 mg/m³

Lithuania OEL - TWA
- 2 mg/m³
- 1 mg/m³

Netherlands OEL - TWA
- 0.25 mg/m³

OSHA - Final PELs - Table Z-3 Mineral D:
- 20 mppcf

Poland OEL - TWA
- 4.0 mg/m³
- 1.0 mg/m³

Portugal OEL - TWA
- 2 mg/m³

Romania OEL - TWA
- 2 mg/m³

Slovakia OEL - TWA
- 2 mg/m³
- 10 mg/m³

Slovenia OEL - TWA
- 2 mg/m³

Spain OEL - TWA
- 2 mg/m³

Sweden OEL - TWAs
- 2 mg/m³
- 1 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Controls**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

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**Sodium chloride**

- Latvia OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 5 mg/m³

**Sugar**

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Estonia OEL - TWA: 10 mg/m³
- France OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Latvia OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 10 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Slovakia OEL - TWA: 6 mg/m³
- Spain OEL - TWA: 10 mg/m³

**Magnesium stearate**

- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

**Ascorbic acid (Vitamin C)**

- Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

**Naltrexone hydrochloride**

- Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

**Sodium chloride**

- Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

**Morphine Sulfate**

- Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Hard-gelatin Capsule

**Color:** Blue, blue violet yellow, pink, Light peach, green

**Odor:** No data available.

**Molecular Formula:** Mixture

**Odor Threshold:** No data available.

**Molecular Weight:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

**Partition Coefficient: (Method, pH, Endpoint, Value)** No data available

**Ammonio methacrylate coploymer**

**Ethylcellulose**

**Hydroxypropyl cellulose**

**Ascorbic acid (Vitamin C)**

**Methacrylic Acid Copolymer, Type C**

**Naltrexone hydrochloride**

**Morphine Sulfate**

**Sodium lauryl sulfate**

**Talc (non-asbestiform)**

**Magnesium stearate**

**Sodium chloride**

**Sugar**

**Decomposition Temperature (°C):** No data available.
SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with Sequestered Naltrexone Hydrochloride Capsules
Revision date: 15-Aug-2018
Version: 2.3

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:
The information included in this section describes the potential hazards of the individual ingredients.

Long Term:
Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects:
Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia. Additionally symptoms of dependence/withdrawal may occur. Secreted in human breast milk. May cause harm to breastfed babies.

Acute Toxicity: (Species, Route, End Point, Dose)

- **Ascorbic acid (Vitamin C)**
  - Rat Oral LD50 11.9 g/kg

- **Naltrexone hydrochloride**
  - Rat Oral LD50 1450 mg/kg

- **Morphine Sulfate**
  - Rat Oral LD50 461 mg/kg
  - Rat Para-periosteal LD50 70mg/kg
  - Rat Intraperitoneal LD50 235mg/kg
  - Mouse Oral LD50 600mg/kg
  - Mouse Intravenous LD50 156mg/kg

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11. TOXICOLOGICAL INFORMATION

Sodium lauryl sulfate
Rat  Oral  LD50  1288 mg/kg

Talc (non-asbestiform)
Rat  Oral  LD50  > 1600 mg/kg

Magnesium stearate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 2000 mg/m³

Sodium chloride
Rat  Oral  LD50  3000 mg/kg
Mouse  Oral  LD50  4000 mg/kg

Sugar
Rat  Oral  LD50  29700 mg/kg
Mouse  Oral  LD50  14000mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium lauryl sulfate
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild  Moderate
Skin Sensitization - GPMT  Guinea Pig  Negative
Skin Sensitization - LLNA  Mouse  Negative

Sodium chloride
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Morphine Sulfate
18 Week(s)  Rat  Oral  60 g/kg  LOAEL  Lungs
15 Day(s)  Rat  Subcutaneous  3144 mg/kg  LOAEL  Kidney, Ureter, Bladder
9 Week(s)  Rat  Subcutaneous  3150 mg/kg  LOAEL

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Naltrexone hydrochloride
Fertility and Embryonic Development  Rat  Oral  30 mg/kg/day  LOAEL  Embryotoxicity
Fertility and Embryonic Development  Rabbit  Oral  60 mg/kg/day  LOAEL  Embryotoxicity
Embryo / Fetal Development  Rat  Oral  200 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  200 mg/kg/day  NOAEL  Not Teratogenic

Morphine Sulfate

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11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development: Mouse, Subcutaneous, 0.15 mg/kg, LOAEL, Teratogenic
Embryo / Fetal Development: Hamster, Subcutaneous, 35 mg/kg, LOAEL, Teratogenic
Embryo / Fetal Development: Mouse, Oral, 200 mg/kg, LOAEL, Teratogenic
Embryo / Fetal Development: Rat, Subcutaneous, 35 mg/kg, LOAEL, Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Naltrexone hydrochloride
- In Vitro Unscheduled DNA Synthesis: Human, Positive
- Mitotic Gene Conversion: Bacteria, Negative
- Bacterial Mutagenicity (Ames): Salmonella, Equivocal
- In Vivo Chromosome Aberration: Mouse, Negative

Morphine Sulfate
- In Vivo Micronucleus: Mouse, Positive
- In Vivo Chromosome Aberration: Mouse Lymphocytes, Positive
- In Vitro Direct DNA Damage: Human Lymphocytes, Positive
- In Vitro Chromosome Aberration: Mouse, Negative
- Dominant Lethal Assay: Drosophila, Negative

Sodium lauryl sulfate
- Bacterial Mutagenicity (Ames): Salmonella, Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Naltrexone hydrochloride
- 2 Year(s): Mouse, Oral, NOAEL, Not carcinogenic
- 2 Year(s): Rat, Oral, 100 mg/kg/day, LOAEL, Tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Talc (non-asbestiform)
- IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sodium lauryl sulfate
- Oncorhynchus mykiss (Rainbow Trout): LC50 96 Hours, 3.6 mg/L

Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
Mobility in Soil: No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:  Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Ascorbic acid (Vitamin C)
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register:
  EU EINECS/ELINCS List: 200-066-2

Dibutyl sebacate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 203-672-5

Ethylcellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
### 15. REGULATORY INFORMATION

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**Version:** 2.3
15. REGULATORY INFORMATION

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Morphine Sulfate

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Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
- Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
- Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet