



# SAFETY DATA SHEET

Revision date: 15-Aug-2018

Version: 2.3

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

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

## 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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**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**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Naltrexone hydrochloride	16676-29-2	240-723-0	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362)	0.75
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Sugar	57-50-1	200-334-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Morphine Sulfate	64-31-3	200-582-8	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362) Muta. 2 (H341)	18

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	Not Listed	*
Dibutyl sebacate	109-43-3	203-672-5	Not Listed	*
Ethylcellulose	9004-57-3	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Methacrylic Acid Copolymer, Type C	Not Assigned	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

**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**

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### 4. FIRST AID MEASURES

#### Description of First Aid Measures

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 5. FIRE FIGHTING MEASURES

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

#### Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
<b>Fire / Explosion Hazards:</b>	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

<b>Measures for Cleaning / Collecting:</b>	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.
<b>Additional Consideration for Large Spills:</b>	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

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### 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/m<sup>3</sup>  
Lithuania OEL - TWA 10 mg/m<sup>3</sup>

#### Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m<sup>3</sup>

#### Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA) 2 mg/m<sup>3</sup>  
Australia TWA 2.5 mg/m<sup>3</sup>  
Austria OEL - MAKs 2 mg/m<sup>3</sup>  
Belgium OEL - TWA 2 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 1.0 fiber/cm<sup>3</sup>  
6.0 mg/m<sup>3</sup>  
3.0 mg/m<sup>3</sup>  
Czech Republic OEL - TWA 2.0 mg/m<sup>3</sup>  
Denmark OEL - TWA 0.3 fiber/cm<sup>3</sup>  
Finland OEL - TWA 0.5 fiber/cm<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
2 mg/m<sup>3</sup>  
Hungary OEL - TWA 2 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
0.8 mg/m<sup>3</sup>  
Lithuania OEL - TWA 2 mg/m<sup>3</sup>  
1 mg/m<sup>3</sup>  
Netherlands OEL - TWA 0.25 mg/m<sup>3</sup>  
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf  
Poland OEL - TWA 4.0 mg/m<sup>3</sup>  
1.0 mg/m<sup>3</sup>  
Portugal OEL - TWA 2 mg/m<sup>3</sup>  
Romania OEL - TWA 2 mg/m<sup>3</sup>  
Slovakia OEL - TWA 2 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Slovenia OEL - TWA 2 mg/m<sup>3</sup>  
Spain OEL - TWA 2 mg/m<sup>3</sup>  
Sweden OEL - TWAs 2 mg/m<sup>3</sup>  
1 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	2 mg/m <sup>3</sup>
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**Sodium chloride**

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

**Sugar**

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

**Magnesium stearate**

Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

**Ascorbic acid (Vitamin C)**

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

**Naltrexone hydrochloride**

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

**Sodium chloride**

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

**Morphine Sulfate**

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

**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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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Hard-gelatin Capsule	<b>Color:</b>	Blue, blue violet yellow, pink, Light peach, green
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Ammonio methacrylate copolymer</b>	No data available		
<b>Ethylcellulose</b>	No data available		
<b>Hydroxypropyl cellulose</b>	No data available		
<b>Ascorbic acid (Vitamin C)</b>	No data available		
<b>Methacrylic Acid Copolymer, Type C</b>	No data available		
<b>Naltrexone hydrochloride</b>	No data available		
<b>Morphine Sulfate</b>	No data available		
<b>Sodium lauryl sulfate</b>	No data available		
<b>Talc (non-asbestiform)</b>	No data available		
<b>Magnesium stearate</b>	No data available		
<b>Sodium chloride</b>	No data available		
<b>Sugar</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		

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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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#### 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/m<sup>3</sup>

#### 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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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

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### 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:	Present
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

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EU EINECS/ELINCS List	Not Listed
<b>Hydroxypropyl cellulose</b>	
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	Not Listed
<b>Methacrylic Acid Copolymer, Type C</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Naltrexone hydrochloride</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	240-723-0
<b>Sodium lauryl sulfate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1
<b>Talc (non-asbestiform)</b>	
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	238-877-9
<b>Sodium chloride</b>	
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	231-598-3
<b>Sugar</b>	
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:	Present
EU EINECS/ELINCS List	200-334-9
<b>Magnesium stearate</b>	

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<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3

#### Morphine Sulfate

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>U.S. Drug Enforcement Administration:</b>	Schedule II
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	200-582-8

**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.

**Revision date:** 15-Aug-2018

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**End of Safety Data Sheet**