



SAFETY DATA SHEET

Revision date: 23-Dec-2016

Version: 2.2

Page 1 of 12

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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 2 of 12

Version: 2.2



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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 3 of 12

Version: 2.2

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 fire fighting 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. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 4 of 12

Version: 2.2

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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 5 of 12

Version: 2.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs 2 mg/m³

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

ACGIH Threshold Limit Value (TWA) 10 mg/m³
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)

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.

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 6 of 12

Version: 2.2

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.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	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)			
Ammonio methacrylate copolymer	No data available		
Ethylcellulose	No data available		
Hydroxypropyl cellulose	No data available		
Ascorbic acid (Vitamin C)	No data available		
Methacrylic Acid Copolymer, Type C	No data available		
Naltrexone hydrochloride	No data available		
Morphine Sulfate	No data available		
Sodium lauryl sulfate	No data available		
Talc (non-asbestiform)	No data available		
Magnesium stearate	No data available		
Sodium chloride	No data available		
Sugar	No data available		
Decomposition Temperature (°C):	No data available.		

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 7 of 12

Version: 2.2

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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 8 of 12

Version: 2.2

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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 9 of 12

Version: 2.2

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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 10 of 12

Version: 2.2

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

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with
Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 11 of 12

Version: 2.2

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
Hydroxypropyl cellulose	
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
Methacrylic Acid Copolymer, Type C	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Naltrexone hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	240-723-0
Sodium lauryl sulfate	
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
Talc (non-asbestiform)	
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
Sodium chloride	
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
Sugar	
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

Magnesium stearate

SAFETY DATA SHEET

Material Name: Morphine Sulfate Extended-Release with Sequestered Naltrexone Hydrochloride Capsules
Revision date: 23-Dec-2016

Page 12 of 12

Version: 2.2

15. REGULATORY INFORMATION

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	209-150-3

Morphine Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
U.S. Drug Enforcement Administration:	Schedule II
Australia (AICS):	Present
EU EINECS/ELINCS List	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 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 23-Dec-2016
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet