



SAFETY DATA SHEET

Revision date: 26-Aug-2016

Version: 3.0

Page 1 of 14

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

Product Identifier

Material Name: Oxycodone hydrochloride and Naltrexone hydrochloride extended-release capsules

Trade Name: TROXYCA ER

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

Reproductive Toxicity: Category 1B
Effects on or via lactation

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements: P201 - Obtain special instructions before use
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
P281 - Use personal protective equipment as required
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: Oxycodone hydrochloride and Naltrexone hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 2 of 14

Version: 3.0



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	%
Diethyl phthalate	84-66-2	201-550-6	Not Listed	*
Naltrexone hydrochloride	16676-29-2	240-723-0	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362)	1-2
Oxycodone hydrochloride	124-90-3	204-717-1	Acute Tox. 4, H302	10-11
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Sugar	57-50-1	200-334-9	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ammonio methacrylate copolymer	33434-24-1	Not Listed	Not Listed	*
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	Not Listed	*
Dibutyl sebacate	109-43-3	203-672-5	Not Listed	0
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	*
Gelatin	9000-70-8	232-554-6	Not Listed	*
Black ink	NOT ASSIGNED	Not Listed	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.

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 3 of 14

Version: 3.0

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 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.

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 4 of 14

Version: 3.0

7. HANDLING AND STORAGE

Precautions for Safe Handling

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 ³
Lithuania OEL - TWA	10 mg/m ³

Diethyl phthalate

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³
Austria OEL - MAKs	3 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Denmark OEL - TWA	3 mg/m ³
Estonia OEL - TWA	3 mg/m ³
Finland OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	5 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
Lithuania OEL - TWA	3 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Russia OEL - TWA	0.5 mg/m ³
Slovenia OEL - TWA	3 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3 mg/m ³
Switzerland OEL - TWAs	5 mg/m ³

Sodium lauryl sulfate

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

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 5 of 14

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL -TWAs	1000 mg/m ³
Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	6.0 mg/m ³
	3.0 mg/m ³
Czech Republic OEL - TWA	2.0 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³
Greece OEL - TWA	10 mg/m ³
	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	0.8 mg/m ³
Lithuania OEL - TWA	2 mg/m ³
	1 mg/m ³
Netherlands OEL - TWA	0.25 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m ³
	1.0 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
	10 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³
	1 mg/m ³
Switzerland OEL -TWAs	2 mg/m ³
Sugar	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELS - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 6 of 14

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
	5 mg/m ³

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

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)

Oxycodone hydrochloride

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: Oxycodone hydrochloride and Naltrexone hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 7 of 14

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands:	Impervious disposable gloves (e.g. Nitrile, etc.) (double 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 goggles as minimum protection. (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:	Various
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)	

Hydroxypropyl cellulose

No data available

Talc (non-asbestiform)

No data available

Ascorbic acid (Vitamin C)

No data available

Ammonio methacrylate copolymer

No data available

Ethylcellulose

No data available

Methacrylic Acid Copolymer, Type C

No data available

Polyethylene glycol

No data available

Sodium lauryl sulfate

No data available

Magnesium stearate

No data available

Sugar

No data available

Titanium dioxide

No data available

Gelatin

No data available

Black Iron Oxide

No data available

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 8 of 14

Version: 3.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Ferric oxide yellow

No data available

Black ink

No data available

Naltrexone hydrochloride

No data available

Oxycodone hydrochloride

No data available

Decomposition Temperature (°C): No data available.

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)

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 9 of 14

Version: 3.0

11. TOXICOLOGICAL INFORMATION

Ascorbic acid (Vitamin C)

Rat Oral LD50 11.9 g/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Sugar

Rat Oral LD50 29700 mg/kg

Mouse Oral LD50 14000mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

Black Iron Oxide

Rat Oral LD50 >1000 mg/kg

Naltrexone hydrochloride

Rat Oral LD50 1450 mg/kg

Oxycodone hydrochloride

Mouse Oral LD50 482 mg/kg

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

Polyethylene glycol

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Sodium lauryl sulfate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild Moderate

Skin Sensitization - GPMT Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

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

Oxycodone hydrochloride

28 Day(s) Rat Oral 4 mg/kg/day NOAEL Central nervous system

3 Month(s) Dog Oral 1 mg/kg/day NOAEL Central Nervous System

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

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 10 of 14

Version: 3.0

11. TOXICOLOGICAL INFORMATION

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

Oxycodone hydrochloride

Fertility and Embryonic Development	Rat	Oral 8 mg/kg/day	NOAEL	Negative, Not teratogenic
Fertility and Embryonic Development	Rabbit	Oral 125 mg/kg/day	NOAEL	Negative, Not Teratogenic
Reproductive & Fertility	Rat	Oral 2 mg/kg/day	NOAEL	Neonatal toxicity

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

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
-------------------------------	-------------------	----------

Naltrexone hydrochloride

<i>In Vitro</i> Unscheduled DNA Synthesis	Human	Positive
Mitotic Gene Conversion	Bacteria	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Equivocal
<i>In Vivo</i> Chromosome Aberration	Mouse	Negative

Oxycodone hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Not specified	Positive
<i>In Vivo</i> Micronucleus	Not specified	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)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

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

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	3.6 mg/L
--	------	----------	----------

Persistence and Degradability: No data available

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 11 of 14

Version: 3.0

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.

Diethyl phthalate
RCRA - U Series Wastes Listed

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

Ammonio methacrylate copolymer	
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

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

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 12 of 14

Version: 3.0

15. REGULATORY INFORMATION

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
Diethyl phthalate	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Present
	201-550-6
Ethylcellulose	
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
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
Oxycodone hydrochloride	
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	204-717-1

Sodium lauryl sulfate

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 13 of 14

Version: 3.0

15. REGULATORY INFORMATION

<p>CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present Schedule 6 205-788-1</p>
<p>Polyethylene glycol CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present Schedule 2 Schedule 3 Not Listed</p>
<p>Talc (non-asbestiform) CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present 238-877-9</p>
<p>Sugar CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present Present 200-334-9</p>
<p>Ferric oxide yellow CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present 257-098-5</p>
<p>Gelatin CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present 232-554-6</p>
<p>Titanium dioxide CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b)</p>	<p>Not Listed carcinogen 9/2/2011 airborne, unbound particles of respirable size Present</p>

SAFETY DATA SHEET

Material Name: Oxycodone hydrochloride and Naltrexone
hydrochloride extended-release capsules
Revision date: 26-Aug-2016

Page 14 of 14

Version: 3.0

15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

Black Iron Oxide

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	215-277-5

Black ink

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Magnesium stearate

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

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

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 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties.

Revision date: 26-Aug-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