



MATERIAL SAFETY DATA SHEET

Revision date: 21-Jul-2011

Version: 2.0

Page 1 of 9

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)

Trade Name: DOLCONTIN, ALGEDOL; CONTALGIN; MORPHOLAR
Chemical Family: Not determined
Intended Use: Pharmaceutical active used as opioid analgesic

2. HAZARDS IDENTIFICATION

Appearance: Tablets, varying in color depending on strength
Signal Word: WARNING

Statement of Hazard: May cause harm to the unborn child.
May cause harm to breastfed babies.
Suspected of causing genetic defects.

Additional Hazard Information:

Short Term: May be harmful if swallowed. (based on components) Dust may cause irritation if tablets are crushed or broken

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.

EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:

R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R68 - Possible risk of irreversible effects.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 2 of 9
Version: 2.0

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	EU Classification	%
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Morphine Sulfate	64-31-3	200-582-8	Xn;R22 Muta.Cat.3;R68 Repr.Cat.2;R61 R64	3-20

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hydroxyethyl cellulose	9004-62-0	Not Listed	Not Listed	*
Purified water	7732-18-5	231-791-2	Not Listed	*
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Film coating	NOT ASSIGNED	Not Listed	Not Listed	*
Cetearyl alcohol	8005-44-5	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 3 of 9
Version: 2.0

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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

General 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.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
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

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 4 of 9
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 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 inhalable fraction
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 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
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
	10 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³
	5 mg/m 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

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 5 of 9
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sweden OEL - TWAs
2 mg/m³
1 mg/m³

Morphine Sulfate

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

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Tablet

Color:

Various According to product specification

Molecular Formula:

Mixture

Molecular Weight:

Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under normal conditions of use.

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

11. TOXICOLOGICAL INFORMATION

General Information:

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

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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Titanium dioxide

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 6 of 9
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Morphine Sulfate

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

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

Polyethylene glycol

Eye Irritation Rabbit Mild
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))

Morphine Sulfate

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)

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

Carcinogen Status: See below

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 7 of 9
Version: 2.0

12. ECOLOGICAL INFORMATION

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

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

EU Symbol: Xn
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 3

EU Risk Phrases:
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May cause harm to the unborn child.
May cause harm to breastfed babies.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 8 of 9
Version: 2.0

15. REGULATORY INFORMATION

WHMIS hazard class:

D1b toxic materials

D2a very toxic materials



Hydroxyethyl cellulose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Purified water

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 231-791-2

Lactose NF, anhydrous

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 200-559-2

Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 236-675-5

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 238-877-9

Morphine Sulfate

U.S. Drug Enforcement Administration: Schedule II
Australia (AICS): Present
EU EINECS/ELINCS List 200-582-8

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 21-Jul-2011

Page 9 of 9
Version: 2.0

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

R68 - Possible risks of irreversible effects.

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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communication
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