



MATERIAL SAFETY DATA SHEET

Revision date: 19-Oct-2007

Version: 1.0

Page 1 of 9

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

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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.
Possible mutagen

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.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 2 of 9
Version: 1.0

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	Classification	%
Morphine Sulfate	64-31-3	200-582-8	Xn;R22 Muta.Cat.3;R68 Repr.Cat.2;R61 R64	3-20
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9 EEC No. 456-230-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	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.

5. FIRE FIGHTING MEASURES

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 3 of 9
Version: 1.0

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). Releases to the environment should be avoided.
Storage Conditions:	Store as directed by product packaging.
Storage Temperature:	At or below 25°C (77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA	
Belgium OEL - TWA	= 10 mg/m ³ TWA	
Ireland OEL - TWAs	= 10 mg/m ³ TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m ³ IPRV	
Portugal OEL - TWA	= 10 mg/m ³ TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m ³ VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m ³ LLV	

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Austria OEL - MAKs	= 6 mg/m ³ MAK
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 4 of 9
Version: 1.0

Denmark OEL - TWA	= 6 mg/m ³ TWA
Estonia OEL - TWA	= 5 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 5 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
Latvia OEL - TWA	= 10 mg/m ³ TWA
Lithuania OEL - TWA	= 5 mg/m ³ IPRV
Netherlands OEL - TWA	= 10 mg/m ³ MAC
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
Poland OEL - TWA	= 10.0 mg/m ³ NDS <2% free crystalline silica and containing no asbestos
Portugal OEL - TWA	= 10 mg/m ³ TWA
Romania OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 5 mg/m ³ LLV

Polyethylene glycol

Austria OEL - MAKs	= 1000 mg/m ³ MAK
Germany - TRGS 900 - TWAs	= 1000 mg/m ³ TWA
Netherlands OEL - TWA	= 1000 mg/m ³ MAC
Slovakia OEL - TWA	= 1000 mg/m ³ TWA
Slovenia OEL - TWA	= 1000 mg/m ³ TWA

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	= 2.5 mg/m ³ TWA containing no asbestos fibers
Austria OEL - MAKs	= 2 mg/m ³ MAK asbestos-free fibers
Belgium OEL - TWA	= 2 mg/m ³ TWA
Bulgaria OEL - TWA	= 1.0 f/cm ³ TWA containing <2% uncombined crystalline silicon dioxide
	= 3.0 mg/m ³ TWA
	= 6.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 10 mg/m ³ TWA
	= 2.0 mg/m ³ TWA
Denmark OEL - TWA	= 0.3 fiber/cm ³ TWA
Estonia OEL - TWA	= 0.5 mg/m ³ TWA
	= 1 mg/m ³ TWA
Finland OEL - TWA	= 0.5 fibers/cm ³ TWA
	= 5 mg/m ³ TWA
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 2 mg/m ³ TWA
Hungary OEL - TWA	= 2 mg/m ³ TWA
Ireland OEL - TWAs	= 0.8 mg/m ³ TWA
	= 10 mg/m ³ TWA
Netherlands OEL - TWA	= 1 mg/m ³ MAC
OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
Poland OEL - TWA	= 1.0 mg/m ³ NDS
	= 4.0 mg/m ³ NDS
Portugal OEL - TWA	= 2 mg/m ³ TWA
Romania OEL - TWA	= 2 mg/m ³ TWA

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 5 of 9
Version: 1.0

Slovakia OEL - TWA	= 10 mg/m ³ TWA
	= 2 mg/m ³ TWA
Slovenia OEL - TWA	= 2 mg/m ³ TWA
Spain OEL - TWA	= 2 mg/m ³ VLA-ED this value is for the particulated matter that is free from asbestos and contains less than 1% of crystalline silica
Sweden OEL - TWAs	= 1 mg/m ³ LLV
	= 2 mg/m ³ LLV

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Morphine Sulfate

Pfizer Occupational Exposure Band (OEB): OEB3 (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.

Personal Protective Equipment:

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

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

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)

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 6 of 9
Version: 1.0

Magnesium stearate

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

Titanium dioxide

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 Intravenous 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
OSHA: Present

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 7 of 9
Version: 1.0

Talc (non-asbestiform)

IARC:

Group 3

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

Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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.
Possible mutagen

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 8 of 9
Version: 1.0

Canada - WHMIS: Classifications

WHMIS hazard class:

D1b toxic materials

D2a very toxic materials



Morphine Sulfate

Australia (AICS): Present
EU EINECS/ELINCS List 200-582-8

Hydroxyethyl cellulose

Inventory - United States TSCA - Sect. 8(b) XU
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

Magnesium stearate

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

Lactose NF, anhydrous

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-559-2

Hydroxypropyl cellulose

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

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 238-877-9
EEC No. 456-230-0

MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Page 9 of 9
Version: 1.0

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.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet