



MATERIAL SAFETY DATA SHEET

Revision date: 08-Nov-2007

Version: 1.0

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

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Material Name: Morphine Hydrochloride Oral Solution

Trade Name:	Morphine Mixture; RA-MORPH
Chemical Family:	Not determined
Intended Use:	Pharmaceutical active used as opioid analgesic

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless or pale yellow solution
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. May cause eye irritation. (based on components) .
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: Mutagenic Category 3
Toxic to reproduction, Category 2

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.

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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 hydrochloride	52-26-6	200-136-2	Mut.Cat.3;R68 R64 Repr.Cat.2;R61 Xn;R22	0.1-5
Glycerol	56-81-5	200-289-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Sodium citrate	68-04-2	200-675-3	Not Listed	*
Sodium Methyl p-Hydroxybenzoate (methylparaben sodium)	5026-62-0	225-714-1	Not Listed	*
Water for injection	7732-18-5	231-791-2	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

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.

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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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

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.

Glycerol

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Estonia OEL - TWA	= 10 mg/m ³ TWA
Finland OEL - TWA	= 20 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Greece OEL - TWA	= 10 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
Netherlands OEL - TWA	= 10 mg/m ³ MAC
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
Poland OEL - TWA	= 10 mg/m ³ NDS
Portugal OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

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 hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

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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:	Solution	Color:	Clear, colorless or Pale yellow
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 various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

Citric acid, anhydrous

Rat Oral LD50 3000 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

Morphine hydrochloride

Rat Oral LD50 335 mg/kg
Mouse Oral LD50 745 mg/kg
Rat Subcutaneous LD50 480 mg/kg

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Glycerol

Rat Oral LD 50 12600 mg/kg

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

Citric acid, anhydrous

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Glycerol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Morphine Sulfate

18 Week(s) Rat Oral 60 g/kg LOEL Lungs
15 Day(s) Rat Subcutaneous 3144 mg/kg LOEL Kidney, Ureter, Bladder
9 Week(s) Rat Subcutaneous 3150 mg/kg LOEL

Glycerol

28 Day(s) Rat Oral 16800 mg/kg LOEL Endocrine system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Morphine Sulfate

Embryo / Fetal Development Mouse Subcutaneous 0.15 mg/kg LOEL Teratogenic
Embryo / Fetal Development Hamster Subcutaneous 35 mg/kg LOEL Teratogenic
Embryo / Fetal Development Mouse Oral 200 mg/kg LOEL Teratogenic
Embryo / Fetal Development Rat Subcutaneous 35 mg/kg LOEL Fetotoxicity

Glycerol

Reproductive & Fertility-Males Rat Oral 100 mg/kg LOEL Fertility

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: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

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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: Mutagenic Category 3
Toxic to reproduction, Category 2

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:
S23 - Do not breathe fumes/vapour/spray.
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

Canada - WHMIS: Classifications

WHMIS hazard class:
D1b toxic materials
D2a very toxic materials



Morphine hydrochloride

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Australia (AICS):	Present
EU EINECS/ELINCS List	200-136-2
Citric acid, anhydrous	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1
Sodium citrate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-675-3
Glycerol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-289-5
Sodium Methyl p-Hydroxybenzoate (methylparaben sodium)	
Australia (AICS):	Present
EU EINECS/ELINCS List	225-714-1
Water for injection	
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

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: Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

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

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.

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End of Safety Data Sheet