

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Product Name: **Astramorph/PF**
Manufacturer Name: Distributed / Manufactured by Fresenius Kabi USA, LLC
Address: 1501 East Woodfield Road
Suite 300 East
Schaumburg, IL 60173-5837
General Phone Number: (847) 706-2084
Customer Service Phone Number: (888) 386-1300
Emergency Phone Number: (800) 424-9300
CHEMTREC: For emergencies in the US, call CHEMTREC: 800-424-9300
MSDS Creation Date: January 08, 2009
MSDS Revision Date: January 08, 2012
MSDS Format: According to ANSI Z400.1-2004

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Morphine Sulfate	64-31-3	0.5 mg/mL or 1 mg/mL	
Sodium Chloride	7647-14-5	9 mg/mL	
Water for Injection	7732-18-5	Quantity Sufficient	

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption Injection

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Adverse effects from therapeutic doses include: respiratory depression and/or respiratory arrest, sympathetic hyperactivity, convulsions, dysphoric reactions, toxic psychoses, pruritus, urinary retention, constipation, and headache. Occupational exposure has not been fully investigated

Aggravation of Pre-Existing Conditions: Individuals with allergy to morphine or other opiates, acute bronchial asthma, upper airway obstruction, and individuals whose ability to maintain blood pressure has already been compromised.

SECTION 4 - FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176 or (847) 706-2084.

SECTION 5 - FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 - HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature]. Protect from light. Do not freeze. Retain vial in carton until time of use.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION - EXPOSURE GUIDELINES

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Odor:	Odorless
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Not established.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	2.5 - 6.5
Molecular Formula:	Mixture
Molecular Weight:	758.83
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 - STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 - TOXICOLOGICAL INFORMATION

Morphine Sulfate :

RTECS Number:	QC8750000
Ingestion:	Oral - Rat LD50: 461 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 600 mg/kg [Behavioral - Analgesia]
Teratogenicity:	Pregnancy Category C: Morphine sulfate is not teratogenic in rats at 35 mg/kg/day (thirty-five times the usual human dose) but does result in increased pup mortality and growth retardation at doses that narcotize the animal (> 10 mg/kg/day, ten times the usual human dose). Astramorph/PF should only be given to pregnant women when no other method of controlling pain is available and means are at hand to manage the delivery and perinatal care of the opiate-dependent infant.
Other Toxicological Information:	Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes] Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability] Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion] Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral] Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

Sodium Chloride :

RTECS Number:	VZ4725000
Eye:	Eye - Rabbit Standard Draize test.: 10 mg [Moderate]
Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Inhalation:	Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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SECTION 14 - TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 - REGULATORY INFORMATION

Morphine Sulfate :

EINECS Number:	200-582-8
Canada DSL:	Listed

Sodium Chloride :

TSCA Inventory Status:	Listed
EINECS Number:	231-598-3
Canada DSL:	Listed

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 - ADDITIONAL INFORMATION

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