



# MATERIAL SAFETY DATA SHEET

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Version: 1.0

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

**Pfizer Inc**  
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**Emergency telephone number:**  
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**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Pfizer Ltd**  
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**+00 44 (0)1304 616161**  
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**ChemSafe (24 hours): +44 (0)208 762 8322**

### Material Name: Gentamicin Injection

<b>Trade Name:</b>	Gentamicin Injection
<b>Chemical Family:</b>	Aminoglycoside
<b>Intended Use:</b>	Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless sterile solution  
**Signal Word:** DANGER

**Statement of Hazard:** May cause allergic skin reaction.  
May damage the unborn child.

### Additional Hazard Information:

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys.  
**Known Clinical Effects:** May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Adverse effects most commonly reported in clinical use include effects on hearing, nausea, vomiting, and vertigo (vestibular ototoxicity), nervous system/brain toxicity (neurotoxicity), kidney toxicity (nephrotoxicity). May cause adverse effects on the developing fetus. Serious allergic reactions, including anaphylaxis, have been reported.

**EU Indication of danger:** Irritant  
Toxic to reproduction: Category 1

### EU Hazard Symbols:

Xn



### EU Risk Phrases:

R43 - May cause sensitization by skin contact.  
R63 - Possible risk of harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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## 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	Classification	%
Gentamicin sulfate	1405-41-0	215-778-9	Repr.Cat.1;R61 Xi;R43	1-10

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Edetate disodium	139-33-3	205-358-3	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.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

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### 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). Wash hands and any exposed skin after removal of PPE. 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

- 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:** Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Sterile solution	<b>Color:</b>	Colorless
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Polymerization:** Will not occur

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### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** Strong acids and 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)

##### **Edetate disodium**

Rat Oral LD50 2000-2200 mg/kg

##### **Gentamicin sulfate**

Rat Oral LD50 > 5000 mg/kg

Rat Intravenous LD50 96 mg/kg

Rat Intramuscular LD50 384 mg/kg

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Gentamicin sulfate**

Embryo / Fetal Development Rat Intraperitoneal 375 mg/kg/day LOAEL Developmental toxicity

Prenatal & Postnatal Development Rat Subcutaneous 660 mg/kg/day LOAEL Developmental toxicity

Prenatal & Postnatal Development Rat Subcutaneous 660 mg/kg/day LOAEL Neonatal toxicity

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

##### **Gentamicin sulfate**

DNA Binding Assay *E. coli* 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 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. 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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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## 14. TRANSPORT INFORMATION

## 15. REGULATORY INFORMATION

**EU Symbol:** T  
**EU Indication of danger:** Irritant  
Toxic to reproduction: Category 1

**EU Risk Phrases:**  
R43 - May cause sensitization by skin contact.  
R63 - Possible risk of harm to the unborn child.

**EU Safety Phrases:**  
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
DANGER  
May cause allergic skin reaction.  
May damage the unborn child.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A  
Class D, Division 2, Subdivision B



**Edetate disodium**  
Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 205-358-3

**Water for injection**  
Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
REACH - Annex IV - Exemptions from the obligations of Register: Present  
EU EINECS/ELINCS List 231-791-2

**Gentamicin sulfate**

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### 15. REGULATORY INFORMATION

California Proposition 65	Aminoglycosides- developmental
Australia (AICS):	Listed
EU EINECS/ELINCS List	215-778-9

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

R61 - May cause harm to the unborn child.

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

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

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**End of Safety Data Sheet**