



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.2

Page 1 of 7

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Penicillin G procaine, Dihydrostreptomycin sulfate aqueous injection

Trade Name: Combiotic Injectable Suspension
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Penicillin G procaine	54-35-3	200-205-7	15-20
Lecithin	8002-43-5	232-307-2	*
Sodium formaldehyde sulfoxylate dihydrate	6035-47-8	Not listed	*
Sodium phosphite pentahydrate	13517-23-2	Not listed	*
Procaine hydrochloride	51-05-8	200-077-2	*
Dihydrostreptomycin sulfate	1425-61-2	215-843-1	25-30
Urea (45%)	57-13-6	200-315-5	*

Ingredient	CAS Number	EU EINECS List	%
Sodium citrate, dihydrate	6132-04-3	Not listed	*
Water for injection	7732-18-5	231-791-2	*
Butylparaben	94-26-8	202-318-7	*
Povidone	9003-39-8	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: White to slightly yellow homogeneous suspension
Signal Word: WARNING

Statement of Hazard: May cause allergic reaction.
May cause ototoxicity (harmful effects on the ear).
May cause kidney effects

Additional Hazard Information:

MATERIAL SAFETY DATA SHEET

Material Name: Penicillin G procaine, Dihydrostreptomycin
sulfate aqueous injection
Revision date: 02-Jan-2007

Page 2 of 7

Version: 1.2

Short Term: May cause allergic reactions in susceptible individuals. Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects: Common adverse reactions associated with the clinical use of streptomycin include vestibular ototoxicity (nausea, vomiting, and vertigo); parasthesia of face; rash; fever; urticaria; angioneurotic edema; and eosinophilia. Streptomycin can cause fetal harm (ototoxicity) when administered to a pregnant woman. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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

EU Hazard Symbols:



EU Risk Phrases:

R43 - May cause sensitization by skin contact.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Hazardous Combustion Products: Not known

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

Fire / Explosion Hazards: Not applicable

MATERIAL SAFETY DATA SHEET

Material Name: Penicillin G procaine, Dihydrostreptomycin
sulfate aqueous injection
Revision date: 02-Jan-2007

Page 3 of 7

Version: 1.2

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 spill with absorbent material. 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:** Use only in a well-ventilated area. Avoid contact with skin and clothing. Avoid breathing vapor or mist.
- Storage Conditions:** Store under refrigeration in closed container.
- Storage Temperature:** 2 - 8°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Good general ventilation should be sufficient to control airborne levels. Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

- Hands:** Rubber gloves
- Eyes:** Wear safety glasses or goggles if eye contact is possible.
- Skin:** None required with normal use of this material. Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material. Clean up spills immediately.
- Respiratory protection:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

- Physical State:** Homogenous Suspension **Color:** White to slightly yellow
- Molecular Formula:** Mixture **Molecular Weight:** Mixture
- pH:** 6.3 - 6.7
- Flash Point (Liquid) (°C):** Non-flammable

10. STABILITY AND REACTIVITY

- Stability:** Stable

MATERIAL SAFETY DATA SHEET

Material Name: Penicillin G procaine, Dihydrostreptomycin sulfate aqueous injection

Page 4 of 7

Revision date: 02-Jan-2007

Version: 1.2

Conditions to Avoid: None known
Incompatible Materials: No data available

Hazardous Decomposition Products: No data available
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.

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

Dihydrostreptomycin sulfate

Mouse Oral LD50 > 600 mg/kg
Rat SC LD50 1100 mg/kg
Mouse IP LD50 1380 mg/kg
Rat IV LD50 137 mg/kg

Lecithin

Rat Oral LD50 > 8 ml/kg

Penicillin G procaine

Mouse Oral LD50 > 2000 mg/kg
Rat Oral LD50 > 2000 mg/kg

Povidone

Rat Oral LD50 100 g/kg

Procaine hydrochloride

Rat IP LD50 160 mg/kg
Rat IV LD50 38 mg/kg

Urea (45%)

Rat Oral LD50 8471 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Inhalation Acute Toxicity Allergic reactions might occur based on effects of the individual components.

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

Urea (45%)

Skin Irritation Human Moderate
Eye Irritation Rabbit Moderate

Eye Irritation / Sensitization Skin Irritation / Sensitization

No data available
Streptomycin and penicillins are known to cause contact dermatitis and allergic reactions in sensitive individuals. Hypersensitivity reactions can occur in individuals sensitive to penicillin, streptomycin, and/or other aminoglycosides.

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

Dihydrostreptomycin sulfate

75 Day(s) Monkey Intramuscular 9375 mg/kg/day LOEL None identified

Subchronic Effects

In subchronic oral studies in mice and rats, doses up to 3000 mg/kg of penicillin V potassium resulted in lesions of the glandular stomach and/or forestomach.

MATERIAL SAFETY DATA SHEET

Material Name: Penicillin G procaine, Dihydrostreptomycin sulfate aqueous injection
Revision date: 02-Jan-2007

Page 5 of 7

Version: 1.2

Chronic Effects/Carcinogenicity No evidence of carcinogenicity was seen in long-term animal studies conducted by the US National Toxicology Program (NTP) with penicillin V potassium. Low incidences of non-cancerous lesions in the nasal mucosa, lung and stomach were noted.

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

Dihydrostreptomycin sulfate

Reproductive & Fertility Rat Intramuscular 7500 mg/kg/day LOEL Developmental toxicity

Reproductive Effects Reproductive studies with penicillins in mice, rats, and rabbits revealed no evidence of fertility impairment.

Teratogenicity Streptomycin can cause fetal harm (ototoxicity) when administered to pregnant women. Teratogenicity studies in mice, rats, rabbits, and guinea pigs have not shown adverse effects due to streptomycin administration during pregnancy, with the possible exception of ototoxicity.

Mutagenicity There are negative results reported for bacterial assays and mixed results for mammalian cell assays conducted with penicillins. Penicillins are not generally regarded as mutagenic.

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

Povidone

IARC: Group 3

At increase risk from exposure: Allergy to penicillins, streptomycins, and/or other aminoglycosides. Individuals with impaired kidney function.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Urea (45%)

Daphnia Magna EC-50 24 Hours > 10,000 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

MATERIAL SAFETY DATA SHEET

Material Name: Penicillin G procaine, Dihydrostreptomycin
sulfate aqueous injection
Revision date: 02-Jan-2007

Page 6 of 7

Version: 1.2

15. REGULATORY INFORMATION

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

EU Risk Phrases:
R43 - May cause sensitization by skin contact.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S24 - Avoid contact with skin.
S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May cause allergic reaction.
May cause ototoxicity (harmful effects on the ear).
May cause kidney effects

Canada - WHMIS: Classifications

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



Penicillin G procaine	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-205-7
Lecithin	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-307-2
Sodium citrate, dihydrate	
Australia (AICS):	Present
Water for injection	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
Butylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present

MATERIAL SAFETY DATA SHEET

Material Name: Penicillin G procaine, Dihydrostreptomycin
sulfate aqueous injection
Revision date: 02-Jan-2007

Page 7 of 7

Version: 1.2

Australia (AICS):	Present
EU EINECS List	202-318-7
Povidone	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Procaine hydrochloride	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-077-2
Dihydrostreptomycin sulfate	
EU EINECS List	215-843-1
Urea (45%)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-315-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet