MATERIAL SAFETY DATA SHEET

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

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Material Name: Carbenicillin indanyl sodium film coated tablets

Trade Name: Not determined
Synonyms: GEOCILLIN® carbenicillin indanyl sodium tablets
Chemical Family: Semisynthetic penicillin
Intended Use: Antibacterial

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sodium lauryl sulfate	151-21-3	205-788-1	*
Magnesium stearate	557-04-0	209-150-3	*
Carbenicillin indanyl sodium	26605-69-6	247-845-3	*

Ingredient	CAS Number	EU EINECS List	%
Glycine	56-40-6	200-272-2	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Yellow, capsule-shaped and film coated tables
Signal Word: CAUTION

Eye Contact: None known
Skin Contact: None known
Inhalation: None known
Ingestion: Symptoms of chronic exposure to this material include redness and swelling of the skin, rash, chills, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Sensitization reactions as severe as anaphylaxis or delayed reactions may also occur in susceptible individuals.
Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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.

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. Get medical attention immediately.

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: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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

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 or leak. Wipe up with a damp cloth and place in container for disposal. 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: Review Sections 3, 8 and 12 before proceeding with clean up. Vacuum or sweep material into appropriate recovery container. Close container and move it to a secure holding area.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize dust generation and accumulation. Use only in a well-ventilated area. IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID BREATHING DUST AND AVOID CONTACT WITH EYES, SKIN AND CLOTHING.

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature 25-30 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr:	0.3 mg/m³
Pfizer STEL	0.75 mg/m³

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands:	None required under normal and foreseeable conditions of use.
Eyes:	Not required under normal conditions of use.
Skin:	None required under normal and foreseeable conditions of use.
Respiratory protection:	None required under normal conditions of use. Use dust mask for dusty conditions.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	**Color:**	Yellow
Odor:	Odorless	**Molecular Formula:**	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	Strong oxidizers
Hazardous Decomposition Products:	No data available
Polymerization:	Will not occur

11. TOXICOLOGICAL INFORMATION

NTP:	Not classified
IARC:	Not classified
OSHA:	No

Magnesium stearate

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

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Ingestion Acute Toxicity The acute oral LD50 for the active ingredient is listed in the table, above. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient it contains.

Sodium lauryl sulfate

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Skin Irritation / Sensitization Penicillins are known to cause contact dermatitis and allergic reactions in sensitive individuals. Sensitization reactions may occur suddenly in previously exposed individuals who have never reacted in the past.

Subchronic Effects Subchronic subcutaneous (SC) and intravenous (IV) toxicity studies of carbenicillin were conducted in rats and dogs. In rats, carbenicillin was administered subcutaneously at dose levels of 250, 500, or 1000 mg/kg/day for 13 weeks. No systemic clinical or histological drug-related effects were observed. In dogs, carbenicillin was administered IV at dose levels up to 500 mg/kg/day for 4 weeks and SC at dose levels of 250, 500, or 1000 mg/kg/day for 13 weeks. Severe local swelling, pain and cyst formation occurred in the high-dose animals; moderate to minimal local irritation was evident at 500 and 250 mg/kg, respectively. No systemic clinical or histological changes attributable to carbenicillin were seen.

Chronic Effects/Carcinogenicity No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

Reproductive Effects Carbenicillin had no effect on fertility or reproductive performance in rats at oral doses up to 1000 mg/kg. In a peri- and postnatal study in mice and rats, no adverse effects were seen at doses up to 500 mg/kg/day, subcutaneously.

Teratogenicity No evidence of teratogenicity were observed in mice or rats at subcutaneous dose levels of 100 or 500 mg/kg/day of carbenicillin.

Mutagenicity No studies have been conducted to evaluate the mutagenic potential of this material.

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

At increase risk from exposure: Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.

Additional Information: FDA PREGNANCY CATEGORY B. No adequate and well-controlled studies in pregnant women. Animal studies failed to demonstrate a risk to the fetus. No adequate and well-controlled studies in pregnant women. However, animal studies failed to demonstrate a risk to the fetus or adequate and well-controlled studies in pregnant women failed to demonstrate a risk to the fetus.

12. ECOLOGICAL INFORMATION

Environmental Overview: No environmental effects data are available.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. This material may also be disposed in landfills. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated

Proper shipping name: Carbenicillin indanyl sodium film coated tables

15. REGULATORY INFORMATION

OSHA Label:
CAUTION

Canada - WHMIS: Classifications

WHMIS hazard class:
None required

Glycine

EU EINECS List	200-272-2
Inventory - United States TSCA - Sect. 8(b)	Listed

Sodium lauryl sulfate

EU EINECS List	205-788-1
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

Carbenicillin indanyl sodium

EU EINECS List	247-845-3

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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