



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

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

Material Name: Cilazapril Tablets

Trade Name:	Initiss
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antihypertensive

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Cilazapril	88768-40-5	Not listed	1-5 mg***
Maize starch	9005-25-8	232-679-6	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*
Iron oxide	1309-37-1	215-168-2	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*
Hypromellose	9004-65-3	Not listed	*
Sodium Stearilfumarate	Not assigned	Not listed	*

Additional Information:

* Proprietary

*** per tablet/capsule/lozenge/suppository

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

Statement of Hazard: Antihypertensive drug: has blood pressure-lowering properties
May cause harm to the unborn child.

Additional Hazard Information:

Short Term: Not acutely toxic (based on components)
Long Term: Increased frequencies of major malformations, minor anomalies, growth abnormalities, mental deficiency, and malignancies have been reported among children born to women who took phenytoin during pregnancy.

Known Clinical Effects: Due to intended use, dangerous lowering of blood pressure can occur.

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EU Indication of danger: Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:

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 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: Remove clothing and wash affected skin with soap and water. 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. 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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 spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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.

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7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Maize starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA

ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA

Australia TWA = 2.5 mg/m³ TWA containing no asbestos fibers

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

Iron oxide

OSHA - Final PELs - TWAs: = 10 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA

Australia TWA = 5 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Individuals with known sensitivity to penicillin should wear protective gloves to avoid skin contact.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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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: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Lactose

Rat Oral LD50 > 10 g/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD 50 50 mg/kg

Cilazapril

Rat Oral LD 50 > 5000 mg/kg

Rat Intravenous LD 50 > 30 mg/kg

Rat Intraperitoneal LD 50 830 mg/kg

Mouse Intravenous LD 50 > 30 mg/kg

Mouse Intraperitoneal LD 50 1300 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 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.

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

Cilazapril

Embryo / Fetal Development Rat Oral 5 mg/kg/day LOAEL Developmental toxicity

Embryo / Fetal Development Rat Oral 50 mg/kg/day LOAEL Embryotoxicity

Peri-/Postnatal Development Rat Oral 50 mg/kg/day LOAEL Developmental toxicity

Embryo / Fetal Development Rat Oral 400 mg/kg/day LOAEL Developmental toxicity

Carcinogen Status: See below

Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

Iron oxide

IARC: Group 3

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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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

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

EU Risk Phrases: R61 - May cause harm to the unborn child.

EU Safety Phrases: S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Antihypertensive drug: has blood pressure-lowering properties
May cause harm to the unborn child.

Canada - WHMIS: Classifications

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



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Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Maize starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Iron oxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-168-2

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet