



MATERIAL SAFETY DATA SHEET

Revision date: 11-Jun-2008

Version: 1.3

Page 1 of 11

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

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Material Name: Isosorbide Dinitrate Hard Gelatin Capsules

Trade Name:	Iso Mack Retard Capsules
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

2. HAZARDS IDENTIFICATION

Appearance: Capsules
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.

Additional Hazard Information:

Short Term: May be harmful if swallowed. (based on components) . May cause slight irritation . Antihypertensive drug: has blood pressure-lowering properties

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects: The most frequent adverse effects seen during clinical use are headache, chest pain, and dizziness.

EU Indication of danger: Toxic to Reproduction; Category 3

EU Hazard Symbols:

Xn



EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 2 of 11
Version: 1.3

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	%
Isosorbide Dinitrate	87-33-2	201-740-9	Xn;R22 Repr.Cat.3;R63	11.1-23.3
Ethanol	64-17-5	200-578-6	F;R11	<1.0
Sucrose	57-50-1	200-334-9	Not Listed	*
Maize starch	9005-25-8	232-679-6	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9 EEC No. 456-230-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Shellac	9000-59-3	232-549-9	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
Ethylcellulose	9004-57-3	Not listed	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: Formation of toxic gases is possible during heating or fire.

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 3 of 11
Version: 1.3

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.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

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

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 4 of 11
Version: 1.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ethanol

ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m ³ TWA
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany - TRGS 900 - TWAs	= 500 ppm TWA = 960 mg/m ³ TWA
Germany (DFG) - MAK	= 500 ppm MAK = 960 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	= 1000 ppm TWA = 1900 mg/m ³ TWA
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 1000 ppm TWA = 1900 mg/m ³ TWA
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	= 1000 mg/m ³ LLV = 500 ppm LLV

Sucrose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	= 10 mg/m ³ TWA
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Maize starch

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	Listed

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 5 of 11
Version: 1.3

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	= 10 mg/m ³ TWA = 4 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	= 2.5 mg/m ³ TWA containing no asbestos fibers
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	= 0.8 mg/m ³ TWA = 10 mg/m ³ TWA
Netherlands OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	= 1 mg/m ³ LLV = 2 mg/m ³ LLV

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Isosorbide Dinitrate

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 6 of 11
Version: 1.3

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.

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: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

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

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: The information included in this section describes the potential hazards of the individual ingredients.

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 7 of 11
Version: 1.3

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

Isosorbide Dinitrate

Rat Oral LD50 747 mg/kg
Rat Intravenous LD50 > 40 mg/kg
Rat Intraperitoneal LD50 670 mg/kg
Mouse Oral LD50 1050 mg/kg
Mouse Intravenous LD50 > 40 mg/kg

Ethanol

Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m³
Rat Inhalation LC50 10h 20,000 ppm

Lactose

Rat Oral LD50 > 10 g/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Sucrose

Rat Oral LD50 29.7 g/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.

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

Isosorbide Dinitrate

Skin Irritation Rabbit Mild

Ethanol

Eye Irritation Rabbit Severe

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

Isosorbide Dinitrate

6 Month(s) Rat Oral 480 mg/kg/day LOAEL Liver, Central nervous system
6 Month(s) Dog Oral 80 mg/kg/day LOAEL Liver, Central Nervous System

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

Isosorbide Dinitrate

Reproductive & Fertility Rat Oral 25 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Rabbit Intravenous 10 mg/kg NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intravenous 10 mg/kg NOAEL Not Teratogenic
Embryo / Fetal Development Rat Oral 700 mg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 220 mg/kg/day LOAEL Fetotoxicity

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

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 8 of 11
Version: 1.3

Isosorbide Dinitrate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
Chromosome Aberration	Human Lymphocytes	Negative
Micronucleus	Mouse	Negative

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

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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

Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
Rainbow Trout	NPDES	LC50	96 Hours	12,900 mg/L
Fathead minnow	NPDES	LC50	96 Hours	14,200 mg/L

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.

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 9 of 11
Version: 1.3

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction; Category 3

EU Risk Phrases: R63 - Possible risk of 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
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

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



Isosorbide Dinitrate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Schedule 4 201-740-9

Ethanol

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Shellac

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-549-9

Lactose

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

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 10 of 11
Version: 1.3

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Maize starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9 EEC No. 456-230-0

Ethylcellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
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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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

MATERIAL SAFETY DATA SHEET

Material Name: Isosorbide Dinitrate Hard Gelatin Capsules
Revision date: 11-Jun-2008

Page 11 of 11
Version: 1.3

End of Safety Data Sheet