



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

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**CHEMTREC (24 hours): 1-800-424-9300**

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

### Material Name: Metoclopramide Capsules

**Trade Name:** Gastrosil; Gastromax  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as gastric motility regulator.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Metoclopramide	364-62-5	206-662-9	30mg***
Maize starch	9005-25-8	232-679-6	*
Sucrose	57-50-1	200-334-9	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*
Colloidal silicon dioxide	7631-86-9	231-545-4	*

Ingredient	CAS Number	EU EINECS List	%
Ethylcellulose	9004-57-3	Not listed	*
Erythrosine (CI 45430)	16423-68-0	240-474-8	*
Ferric oxide yellow	51274-00-1	257-098-5	*
Gelatin	9000-70-8	232-554-6	*
Shellac	9000-59-3	232-549-9	*

**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:** Orange, yellow capsules .  
**Signal Word:** WARNING

**Statement of Hazard:** May be harmful if swallowed.  
May cause central nervous system effects

**Additional Hazard Information:**  
**Short Term:** Effects of breathing dust are not known. Avoid inhaling this material.

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**Known Clinical Effects:** Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Hypersensitivity reactions may also occur in susceptible individuals.

**EU Indication of danger:** Harmful

**EU Hazard Symbols:**



**EU Risk Phrases:** R22 - Harmful if swallowed.

**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:** 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.

### 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.

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**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:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid generating airborne dust.

**Storage Conditions:** Store at controlled room temperature.

**Storage Temperature:** (15-25°C)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Maize starch

**OSHA - Final PELs - TWAs:** = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA

**ACGIH Threshold Limit Value (TWA)** = 10 mg/m<sup>3</sup> TWA

**Australia TWA** = 10 mg/m<sup>3</sup> TWA

#### Sucrose

**OSHA - Final PELs - TWAs:** = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA

**ACGIH Threshold Limit Value (TWA)** = 10 mg/m<sup>3</sup> TWA

**Australia TWA** = 10 mg/m<sup>3</sup> TWA

#### Talc (non-asbestiform)

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

**ACGIH Threshold Limit Value (TWA)** = 2 mg/m<sup>3</sup> TWA

**Australia TWA** = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

#### Titanium dioxide

**OSHA - Final PELs - TWAs:** = 15 mg/m<sup>3</sup> TWA total

**ACGIH Threshold Limit Value (TWA)** = 10 mg/m<sup>3</sup> TWA

**Australia TWA** = 10 mg/m<sup>3</sup> TWA

#### Colloidal silicon dioxide

**OSHA - Final PELs - Table Z-3 Mineral D:** (80)/(% SiO<sub>2</sub>) mg/m<sup>3</sup> TWA  
= 20 mppcf TWA

**Australia TWA** = 2 mg/m<sup>3</sup> TWA

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

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Capsule	<b>Color:</b>	Yellow orange
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None for the normal use of this material .  
**Incompatible Materials:** None known .

## 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)

#### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

#### Sucrose

Rat Oral LD50 29.7 g/kg

#### Metoclopramide

Rat Oral LD 50 750 mg/kg  
Mouse Oral LD 50 270 mg/kg  
Rat Intraperitoneal LD 50 114 mg/kg

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

#### Erythrosine (CI 45430)

Rat Oral LD50 1840 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))

#### Metoclopramide

Embryo / Fetal Development	Rat	Oral	10 mg/kg/day	NOEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Oral	10 mg/kg/day	NOEL	Not Teratogenic
Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	NOEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	10 mg/kg	NOEL	Not Teratogenic

**Carcinogen Status:** See below

#### Colloidal silicon dioxide

**IARC:** Group 3

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Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 2B  
OSHA: Present

### 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:** Xn  
**EU Indication of danger:** Harmful

**EU Risk Phrases:**  
R22 - Harmful if swallowed.

**EU Safety Phrases:**  
S22 - Do not breathe dust.

**OSHA Label:**  
WARNING  
May be harmful if swallowed.  
May cause central nervous system effects

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
D2b toxic materials

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<b>Metoclopramide</b>	
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS List	206-662-9
<b>Maize starch</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6
<b>Sucrose</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9
<b>Talc (non-asbestiform)</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9
<b>Titanium dioxide</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5
<b>Colloidal silicon dioxide</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4
<b>Ethylcellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Erythrosine (CI 45430)</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	240-474-8
<b>Ferric oxide yellow</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	257-098-5
<b>Gelatin</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6
<b>Shellac</b>	
Inventory - United States TSCA - Sect. 8(b)	Present

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Australia (AICS):  
EU EINECS List

Present  
232-549-9

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

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

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**End of Safety Data Sheet**