



MATERIAL SAFETY DATA SHEET

Revision date: 16-Jun-2011

Version: 1.0

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

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Material Name: Clopidogrel Tablets

Trade Name:	Not applicable
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used as anticoagulant agent

2. HAZARDS IDENTIFICATION

Appearance: Pink film-coated tablet
Signal Word: DANGER

Statement of Hazard: Causes severe skin burns and eye damage.
Toxic to aquatic life with long lasting effects.

Additional Hazard Information:
Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal bleeding, gastrointestinal disturbances, nausea, diarrhea, bleeding, discoloration of skin, fever, pain, swelling, dizziness, difficulty breathing.

EU Classification
EU Indication of danger: Corrosive
Dangerous for the Environment

EU Hazard Symbols:



EU Risk Phrases:

R34 - Causes burns.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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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	EU Classification	%
Clopidogrel bisulfate	120202-66-6	Not Listed	C,R34; N,R51/53	38
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Tablet coating	NOT ASSIGNED	Not Listed	Not Listed	*
Butylated hydroxyanisole	25013-16-5	246-563-8	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Sodium stearyl fumarate	4070-80-8	223-781-1	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.

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

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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 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). Wash thoroughly after handling. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose

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

Silicon dioxide, colloidal NF

Australia TWA	2 mg/m ³
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³ MAK

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(% SiO ₂) mg/m ³ TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

Clopidogrel bisulfate

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

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:	Film-coated tablets	Color:	Pink
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under normal conditions of use.

Conditions to Avoid:

Fine particles (such as dust and mists) may fuel fires/explosions.

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.

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

Clopidogrel bisulfate

Rat Oral LD50 2423 mg/kg

Mouse Oral LD50 2491 mg/kg

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Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Butylated hydroxyanisole

Rat Oral LD50 2000 mg/kg
Mouse Oral LD 50 1100 mg/kg
Rat Intraperitoneal LD 50 881 mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 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.

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

Clopidogrel bisulfate

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Corrosive

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Clopidogrel bisulfate

3 Month(s) Rat Oral 400 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Mouse Oral 400 mg/kg/day LOAEL Liver
1 Year(s) Rat Oral 35 mg/kg/day NOAEL Liver
1 Year(s) Monkey Oral 65 mg/kg/day NOAEL Gastrointestinal system, Liver

Butylated hydroxyanisole

12 Day(s) Rat Oral 3300 mg/kg LOAEL Liver, Blood

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Clopidogrel bisulfate

Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 120 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 100 mg/kg/day NOAEL Maternal Toxicity
Peri-/Postnatal Development Rat Oral 25 mg/kg/day NOAEL Maternal Toxicity

Butylated hydroxyanisole

Embryo / Fetal Development Rat Oral 30 g/kg LOEL Teratogenic

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

Clopidogrel bisulfate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Chromosome Aberration Not specified Negative

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In Vitro Forward Mutation Assay Not specified Negative
In Vivo Micronucleus Mouse Negative

Butylated hydroxyanisole

In Vivo Micronucleus Bone Marrow Negative
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Clopidogrel bisulfate

2 Year(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic
78 Week(s) Mouse Oral 100 mg/kg/day NOAEL Not carcinogenic

Butylated hydroxyanisole

Two Year(s) Rat Oral 728 g/kg/day Gastrointestinal system, Tumors
Two Year(s) Rat Oral 874 g/kg/day Gastrointestinal system, Endocrine system, Tumors

Carcinogen Status:

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

Silicon dioxide, colloidal NF

IARC: Group 3

Butylated hydroxyanisole

IARC: Group 2B
NTP: Listed
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment. Releases to the environment should be avoided.

Mobility, Persistence and Degradability: Not readily biodegradable (4.07 % after 28 days). (Clopidogrel)

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

Clopidogrel bisulfate

Daphnia magna (Water Flea) EC50 48 Hours 8.3 mg/L

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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

The following refers to all modes of transportation unless specified below.

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

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15. REGULATORY INFORMATION

EU Indication of danger: Corrosive
Dangerous for the Environment

EU Risk Phrases:
R34 - Causes burns.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

OSHA Label:

DANGER

Causes severe skin burns and eye damage.
Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B

Class E



Mannitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Lactose NF, anhydrous

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

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9

Butylated hydroxyanisole

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15. REGULATORY INFORMATION

California Proposition 65	carcinogen, initial date 1/1/90
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	246-563-8
Croscarmellose sodium	
Australia (AICS):	Listed
Sodium stearyl fumarate	
EU EINECS/ELINCS List	223-781-1
Silicon dioxide, colloidal NF	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R34 - Causes burns.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Publicly available toxicity information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet