# MATERIAL SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>+00 44 (0)1304 616161</td>
<td>+00 44 (0)1304 616161</td>
</tr>
<tr>
<td>Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322</td>
</tr>
<tr>
<td>Contact E-Mail: <a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td></td>
</tr>
</tbody>
</table>

**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:**

![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):**

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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clopidogrel bisulfate</td>
<td>120202-66-6</td>
<td>Not Listed</td>
<td>C,R34; N,R51/53</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Lactose NF, anhydrous</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Tablet coating</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Butylated hydroxyanisole</td>
<td>25013-16-5</td>
<td>246-563-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Sodium stearyl fumarate</td>
<td>4070-80-8</td>
<td>223-781-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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/m³ TWA
- Australia TWA 10 mg/m³
- 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/m³ total 5 mg/m³
- Portugal OEL - TWA Listed
- Romania OEL - TWA Listed
- Spain OEL - TWA Listed

Silicon dioxide, colloidal NF
- Australia TWA 2 mg/m³
- Austria OEL - MAKs Listed
- Czech Republic OEL - TWA Listed
- Estonia OEL - TWA Listed
- Germany - TRGS 900 - TWAs 4 mg/m³
- Germany (DFG) - MAK 4 mg/m³ MAK

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Film-coated tablets</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Pink</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
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</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>2423 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>2491 mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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
11. TOXICOLOGICAL INFORMATION

Butylated hydroxyanisole

Butylated hydroxyanisole

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

Clopidogrel bisulfate

Butylated hydroxyanisole

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:

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

Clopidogrel bisulfate

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.
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:
- 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

<table>
<thead>
<tr>
<th>Material</th>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Proposition 65</td>
<td></td>
<td>carcinogen, initial date 1/1/90</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td></td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td></td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>246-563-8</td>
<td></td>
</tr>
</tbody>
</table>

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

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.

End of Safety Data Sheet