


**SAFETY DATA SHEET**

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Date: 11/10/2015

Generic Name: Clopidogrel Tablets, USP

Brand Equivalent: PLAVIX®  
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<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Clopidogrel Tablets, USP 75 and 300 mg
<b>Active substance</b>	Clopidogrel Bisulfate
<b>Synonyms</b>	N/A
<b>Formula</b>	$C_{16}H_{16}ClNO_2S \cdot H_2SO_4$
<b>Intended Use</b>	Anticoagulant
<b>Chemical Name</b>	Thieno [3,2-c]pyridine-5(4 <i>H</i> )-acetic acid, $\alpha$ -(2-chlorophenyl)-6,7-dihydro-methyl ester, ( <i>S</i> )-sulfate (1:1) (or) Methyl (+)-( <i>S</i> )- $\alpha$ -( <i>o</i> -chlorophenyl)-6,7-dihydrothieno[3,2-c]pyridine-5(4 <i>H</i> )-acetate, sulfate (1:1)
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-434-2723

<b>2. HAZARDS IDENTIFICATION</b>	
<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Acute toxicity, oral Category 4 Skin corrosion/irritation Category 1 Serious eye damage/eye irritation Category 1
<b>OSHA hazard(s)</b>	Not classified.
<b>Symbol</b>	
<b>Signal word</b>	Danger
<b>Hazard statements</b>	Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage.
<b>Precautionary statements Prevention Response</b>	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/medical professional.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container to an approved disposal site.
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
Clopidogrel Bisulfate	120202-66-6	33.77
Microcrystalline Cellulose, NF	9004-34-6	47.87
Mannitol, USP	69-65-8	7.25
Croscarmellose Sodium, NF	74811-65-7	2.42
Hydroxy Propyl Cellulose, NF	9004-64-2	1.93
Hypromellose, USP	9004-65-3	1.93
Hydrogenated Castor Oil, NF	8001-78-3	1.45
Opadry pink	Not available	3.38
<b><u>Opadry pink contains</u></b>		
Hypromellose, USP 6 cP	9004-65-3	Not applicable
Titanium Dioxide, USP	13463-67-7	
Macrogol / Polyethylene Glycol 400, NF	Not available	
Iron Oxide Red, NF	1309-37-1	

<b>4. FIRST AID MEASURES</b>	
<b>Eye contact</b>	Rinse cautiously with water for several minutes. Call a physician or poison control center immediately.
<b>Skin contact</b>	Take off immediately all contaminated clothing. Rinse skin with water/shower. Call a physician or poison control center immediately. For minor skin contact, avoid spreading material on unaffected skin.
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If exposed or concerned: Get medical attention/advice.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<b>Most important symptoms/effects, acute and delayed</b>	Corrosive effects. May cause temporary blindness and severe eye damage.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Obtain ECG, institute continuous cardiac monitoring and administer oxygen. Monitor liver function. Monitor fluid and electrolyte status. Monitor blood counts. Monitor for signs of hemorrhage and transfuse platelets if needed. For thrombotic thrombocytopenic purpura, treat with plasma exchange. (Poisindex)
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek Guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>Suitable extinguishing media</b>	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

<b>7. HANDLING AND STORAGE</b>	
<b>Precautions for safe handling</b>	Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways. <b>FOR CLINICAL SETTING USE (DRUG PRODUCT):</b> When handling broken or crushed tablets or capsules, ensure worker exposure is below the recommended exposure limit.
<b>Container Requirements</b>	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.
<b>Storage Conditions</b>	Store at 15-30 °C. Protect against light. Keep away from heat, sparks and flames. Do not store near incompatible substances.
<b>Specific use(s)</b>	Refer to Section 1

<b>8. Exposure controls/Personal protection</b>	
<b>Exposure limit(s) Clopidogrel Bisulfate</b>	20 µg/m <sup>3</sup>
<b>Respiratory Protection</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Eye protection</b>	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand protection</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is Protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is corrosive. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
<b>Skin and body Protection</b>	FOR MANUFACTURING PROCESSES (BULK): Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat(EN 340) or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability (EN 1149-1).FOR CLINICAL SETTING USE (DRUG PRODUCT): Follow good chemical hygiene practices when using clinical or consumer presentations. It is recommended that a laboratory coat be worn when handling product.
<b>Environmental exposure controls</b>	Prevent release to drains and waterways.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Thermal hazards</b>	Not available
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where Significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>General Information</b>	
<i>Appearance</i>	
<b>Physical State</b>	solid
<b>Color</b>	pink
<b>Form</b>	film coated tablets
<i>Odour</i>	
<b>Odour</b>	Not available
<b>Odor Threshold</b>	Not available
<b>pH</b>	Not available
<i>Other information</i>	
<b>Bulk density</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Molecular formula</b>	Not applicable
<b>Hydrolysis/Photolysis</b>	Not available
<b>Hygroscopicity</b>	Not available
<b>Molecular Weight</b>	Not applicable
<b>Log Octanol/Water Partition Coeff [log Kow]</b>	Not available
<b>Surface Tension</b>	Not available
<b>pKa</b>	Not available
<b>Particle Size</b>	Not available
<b>Solubility, Water</b>	very slightly soluble
<b>Specific Gravity/ Relative Density</b>	Not available
<b>Viscosity, dynamic</b>	Not available
<b>Viscosity, kinematic</b>	Not available
<b>% Volatile</b>	Not available
<i>Thermal/Stability properties</i>	
<b>Autoignition temperature</b>	Not available
<b>Boiling Point</b>	Not available
<b>Thermal decomposition</b>	Not available
<b>Explosive Limits, LEL</b>	Not available
<b>Explosive limits, UEL</b>	Not available
<b>Explosiveness</b>	Not available
<b>Flammability</b>	Not available
<b>Flash point</b>	Not available
<b>Melting Point</b>	Not available
<b>Oxidizing Potential</b>	Not available
<i>Vapor Properties</i>	
<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Saturated Vapor Concentration</b>	Not available

<b>10. Stability and Reactivity</b>	
<b>stability</b>	
<b>Chemical Stability</b>	Stable under normal conditions
<b>Conditions to Avoid</b>	Not available
<b>Materials to Avoid</b>	alkali metals oxidizing agents, highly oxygenated or halogenated solvents, organic compounds containing reducible functional groups
<b>Hazardous Decomposition products</b>	Hazardous decomposition products: carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), sulphur Oxides (SO <sub>x</sub> ), gaseous hydrogen chloride (HCl).
<b>Hazardous Reactions</b>	None known.

<b>11. Toxicological Information</b>	
<b>Routes of Entry</b>	Ingestion, Inhalation, Eye contact, Skin contact
<b>Eye Irritation</b>	Clopidogrel Bisulfate, Severely irritating to eyes
<b>Respiratory Irritation</b>	Clopidogrel Bisulfate, Respiratory Irritant
<b>Acute Toxicity Study</b>	Due to lack of data the classification is not possible
<b>Repeated Dose Toxicity</b>	Due to lack of data the classification is not possible
<b>Genetic Toxicity</b>	Due to lack of data the classification is not possible
<b>Carcinogenicity</b>	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
<b>Reproductive Toxicity</b>	Due to lack of data the classification is not possible
<b>Developmental Toxicity</b>	Due to lack of data the classification is not possible
<b>Pharmacokinetics/Toxicokinetics</b>	Due to lack of data the classification is not possible
<b>Other Toxicity Information</b>	Due to lack of data the classification is not possible


<b>12. Ecological Information</b>	
<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available
<b>Mobility in soil</b>	Not available
<b>Other adverse effects</b>	Not available

<b>13. Disposal considerations</b>	
<b>Advice On Disposal And Packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
<b>Other information</b>	Disposal by incineration is recommended.

<b>14. Transport Information</b>	
<b>IMDG</b>	
UN/ID No.	UN 3077
Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Clopidogrel Bisulfate)
Class	9
Packing group	III
Labelling	9
EmS	F-AS-F
<b>ICAO/IATA-DGR</b>	
Other information	Not Regulated
<b>ADR</b>	
UN/ID No.	UN 3077
Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Clopidogrel Bisulfate)
Class	9
Packing group	III
Labelling	9
Other information	Special Provisions: 274
<b>RID</b>	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Clopidogrel Bisulfate)
Class	9
Packing group	III
Labelling	9
Other information	Special Provisions: 274
<b>US DOT</b>	
Other information	Not Regulated



<b>15. Regulatory Information</b>	
<b>EINECS/ELINCS/Registration Number</b>	Hydrogenated Castor Oil: 232-292-2 Mannitol: 200-711-8 Microcrystalline Cellulose: 232-674-9 Red Iron Oxide: 215-168-2 Titanium Dioxide: 236-675-5 Carnauba Wax: 232-399-4
<b>Labeling</b>	
<b>R&amp;S Labeling</b>	
<b>Symbol(s)</b>	Xn: Harmful C: Corrosive N: Dangerous for the environment
<b>R-phrase(s)</b>	R22: Harmful if swallowed. R34: Causes burns. R64: May cause harm to breastfed babies. R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
<b>S-phrase(s)</b>	S22: Do not breathe dust. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S38: In case of insufficient ventilation, wear suitable respiratory equipment. S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible). S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/ Safety Data Sheets.
<b>Regulatory Authorizations and Restrictions:</b>	Not available
<b>UN Globally Harmonized System (GHS)</b>	
<b>Classification</b>	Skin Corrosion - Category 1A Serious Eye Damage - Category 1 Effects On Or Via Lactation Specific Target Organ Systemic Toxicity (Single Exposure) - Category 3 Specific Target Organ Systemic Toxicity (Repeated Exposure) – Category 1

	Hazardous To The Aquatic Environment - Chronic Hazard - Category 2
<b>15. Regulatory Information</b>	
<b>Labeling</b>	
<b>Symbol</b>	
<b>Signal Word</b>	Danger
<b>Hazard Statements</b>	<p>Causes severe skin burns and eye damage.</p> <p>Causes serious eye damage.</p> <p>May cause respiratory irritation</p> <p>May cause harm to breast-fed children.</p> <p>Causes damage to organs (blood, liver, gastrointestinal tract, kidney) through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.</p>
<b>Precautionary Statements</b>	<p>Avoid ingestion, inhalation, skin and eye contact. Wear suitable protective clothing, gloves and eye/face protection. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Prevent release to the environment. Pregnant or nursing women should avoid exposure. Prevent release to drains and waterways. Prevent release to the environment.</p>

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available
<b>Prepared on</b>	
<b>Revision</b>	01
<b>Disclaimer</b>	<p>The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.</p>