


SAFETY DATA SHEET

 Date: 11/10/2015

Generic Name: Clopidogrel Tablets, USP

 Brand Equivalent: PLAVIX®

SECTION 1: IDENTIFICATION	
Product Name	Clopidogrel Tablets, USP 75 and 300 mg
Active substance	Clopidogrel Bisulfate
Synonyms	N/A
Formula	C ₁₆ H ₁₆ ClNO ₂ S.H ₂ SO ₄
Intended Use	Anticoagulant
Chemical Name	Thieno [3,2-c]pyridine-5(4 <i>H</i>)-acetic acid, α-(2-chlorophenyl)-6,7-dihydro-methyl ester, (<i>S</i>)-sulfate (1:1) (or) Methyl (+)-(<i>S</i>)-α-(<i>o</i> -chlorophenyl)-6,7-dihydrothieno[3,2-c]pyridine-5(4 <i>H</i>)-acetate, sulfate (1:1)
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Physical hazards	Not classified.
Health hazards	Acute toxicity, oral Category 4 Skin corrosion/irritation Category 1 Serious eye damage/eye irritation Category 1
OSHA hazard(s)	Not classified.
Symbol	
Signal word	Danger
Hazard statements	Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage.
Precautionary statements Prevention Response	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.
Storage	Store locked up.
Disposal	Dispose of contents/container to an approved disposal site.
Hazard(s) not otherwise classified (HNOC)	Not classified.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
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
<u>Opadry pink contains</u>		
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	

4. FIRST AID MEASURES	
Eye contact	Rinse cautiously with water for several minutes. Call a physician or poison control center immediately.
Skin contact	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.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If exposed or concerned: Get medical attention/advice.
Ingestion	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.
Most important symptoms/effects, acute and delayed	Corrosive effects. May cause temporary blindness and severe eye damage.
Indication of immediate medical attention and special treatment needed	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)
General information	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.

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

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	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.

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

8. Exposure controls/Personal protection	
Exposure limit(s) Clopidogrel Bisulfate	20 µg/m ³
Respiratory Protection	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).
Eye protection	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.
Hand protection	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.
Skin and body Protection	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.
Environmental exposure controls	Prevent release to drains and waterways.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Thermal hazards	Not available
Other	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.

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

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


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

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

13. Disposal considerations	
Advice On Disposal And Packaging	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.
Other information	Disposal by incineration is recommended.

14. Transport Information	
IMDG	
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
ICAO/IATA-DGR	
Other information	Not Regulated
ADR	
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
RID	
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
US DOT	
Other information	Not Regulated

15. Regulatory Information	
EINECS/ELINCS/Registration Number	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
Labeling	
R&S Labeling	
Symbol(s)	Xn: Harmful C: Corrosive N: Dangerous for the environment
R-phrase(s)	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.
S-phrase(s)	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.
Regulatory Authorizations and Restrictions:	Not available
UN Globally Harmonized System (GHS)	
Classification	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
15. Regulatory Information	
Labeling	
Symbol	
Signal Word	Danger
Hazard Statements	<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>
Precautionary Statements	<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>

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	
Revision	01
Disclaimer	<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>